



**TECHNICAL SHEETS FOR COORDINATION  
HORIZONTAL RECOMMENDATION FOR USE SHEETS (RfUs)  
STATUS ON SEPTEMBER 2011**

<b>Number CNB/P/ (1)</b>	<b>Revision (Rev)</b>	<b>Keywords</b>	<b>Approval Horizontal Committee of NBs (2)</b>	<b>Approval Standing Committee “PPE”</b>
00.001	01	declaration of conformity	24/06/94	01/07/96
00.002	03	technical file, control and test facilities	31/05/96	03/06/97
00.003	01	EC type examination certificate, withdrawal	24/06/94	01/07/96
00.005	03	type examination certificate	31/05/96	03/06/97
00.006	04	sub-contracting, accreditation, acceptance of test results, competence of laboratories	31/05/96	03/06/97
00.007	03	retention, technical file, samples, liability	31/05/96	03/06/97
00.008	02	user information, availability	24/06/94	01/07/96
00.010	01	user information, conformity assessment	24/06/94	01/07/96
00.011	01	technical file	24/06/94	01/07/96
00.012	04	EC type examination, application	31/05/96	03/06/97
00.013	03	type examination certificate, withdrawal, extension, refusal	31/05/96	01/07/96
00.014	02	certification, modified model	24/06/94	01/07/96
00.015	01	limited series, individual items of PPE	24/06/94	01/07/96
00.016	03	EC type examination procedure, harmonised standards	31/05/96	03/06/97
00.017	01	test reports	24/06/94	01/07/96
00.018	03	standards, deficiencies	31/05/96	03/06/97
00.019	01	user information	24/06/94	01/07/96
00.020	01	testing of materials	24/06/94	01/07/96
00.021	01	type examination certificate, modification of products	24/06/94	01/07/96
00.022	01	identification of test samples	24/06/94	01/07/96
00.023	02	quality control, manufacturer	31/05/96	01/07/96
00.024	02	quality control, checks	31/05/96	01/07/96
00.025	02	quality control, application of CE marking	31/05/96	01/07/96
00.026	02	quality control, time interval	31/05/96	01/07/96
00.029	01	CE marking, categories	24/06/94	20/05/05
00.030	04	article 11 A, necessary checks	27/05/98	20/04/98
00.031	01	article 11 A and B, withdrawal of certificates	02/06/95	01/07/96
00.032	01	manufacturer, authorized representative	02/06/95	01/07/96
00.033	03	category I or II for chemical protective clothing		24/11/98
00.034	02	type examination: contents of technical file, technical documentation	01/06/95	18/11/97
00.036	03	period of obsolescence	27/05/98	20/04/98
00.038	03	components from different manufacturers	27/05/98	20/04/98
00.046	04	marking, standard reference, testing according to prEN	26/05/99	21/06/99
00.048	03	sampling 11 A procedures	04/06/97	20/04/98
00.051	04	use of pictograms	23/02/00	15/01/02
00.052	03	test reports, designation of materials	04/06/97	20/04/98
00.058	03	test reports, materials	04/06/97	20/04/98
00.061	03	slip resistance, type examination certificate		18/11/97
00.064	03	type examination for category I PPE	04/06/97	20/04/98
00.067	02	EC declaration of conformity	27/05/99	29/11/99
00.068	05	revision of standard, validity, EC type examination certificate	26/05/99	21/06/99
00.074	04	article 11A, change of certificate	04/06/97	20/04/98
00.075	04	distribution, type examination certificate	04/06/97	20/04/98
00.077	07	information to users	05/05/06	31/07/06
00.080	02	Production Plant		18/11/97


Number CNB/P/ (1)	Revision (Rev)	Keywords	Approval Horizontal Committee of NBs (2)	Approval Standing Committee "PPE"
00.081	03	interchangeable components, EC type examination	27/05/98	21/06/99
00.086	07	composition of audit team; competency of auditors; knowledge of auditors	03/12/04	30/06/05
00.087	05	quality assurance system	03/12/04	30/06/05
00.088	04	Quality Assurance System, Supervision, Frequency of Audits	05/01/98	20/04/98
00.089	03	11.B(c) ISO 9001/2/3:1994	05/01/98	20/04/98
00.090	03	11.B(b) / 11.A.3 "appropriate tests"	05/01/98	20/04/98
00.092	02	notified body reference, information supplied by the manufacturer	26/05/99	27/05/98
00.093	02	Element, CE marking	27/05/98	27/05/98
00.094	02	harmonised standards, essential requirements, EC type examination	27/05/98	27/05/98
00.095	02	technical file	26/05/99	29/11/99
00.096	06	innocuousness of PPE	04/07/01	15/01/02
00.098	03	conformity to standard	23/02/00	15/01/02
00.099	02	CE marking, separate items of PPE, technical file	27/05/99	29/11/99
00.104	02	category; certification	23/02/00	15/01/02
00.105	02	witnessed testing	27/10/00	15/01/02
00.106	04	re-assessment of approved quality system	02/12/04	30/06/05
00.107	02	sample selection	27/10/00	15/01/02
00.109	03	11.A test clauses	05/05/06	31/07/06
00.113	03	Test and Inspection of Production	12/12/02	11/06/03
00.114	03	manufacturer	05/09/02	11/06/03
00.117	02	information supplied by the manufacturer; sensitising or allergenic substances	05/09/02	11/06/03
00.118	02	categorisation; welding	05/09/02	11/06/03
00.120	01	category III product	05/09/02	11/06/03
00.122	03	retention of representative samples	03/12/04	30/06/05
00.123	03	external testing	03/12/04	30/06/05
00.124	02	boil-and-bite mouth guards	03/12/04	30/06/05
00.125	05	Uniformity of production; Article 11.A	24/06/09	20/04/11
00.126	02	Uncertainty of measurement	26/08/05	31/07/06
00.127	02	Dedicated test method standards	05/05/06	31/07/06
00.128	02	Interchangeable components of breathing apparatus	05/05/06	31/07/06
00.129	02	Interchangeable components of breathing apparatus	05/05/06	31/07/06
00.130	02	Own-brand certificates	05/05/06	31/07/06
00.131	02	Standard template for report content covering annual assessment process	09/02/07	15/07/08
00.132	02	Sizing	09/02/07	15/07/08
00.133	02	Traceability of article 10 technical file documents	09/02/07	15/07/08
00.134	02	Article 11 assessment, EC type examination certificate	09/02/07	15/07/08
00.135	04	11B minimum requirements	18/10/09	20/04/11
00.136	02	EC type examination certificates; validity	17/10/08	26/05/09
00.137	03	Failure of 11A samples	31/08/09	20/04/11
00.139	02	Marking, standard number	19/03/10	20/04/11
00.140	02	Product marking; reference to standards	19/03/10	20/04/11
00.141	02	Information supplied by the manufacturer, address of manufacturer	19/03/10	20/04/11


- (1) : CNB/P/xx.xxx RERev yy = Coordination of Notified Bodies/PPE/Numbering of the RfUs  
R: Recommendation for Use E: English version Rev: Revision yy: Index of the Revision  
(2) : NBs = Notified Bodies

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.001 Revision 01 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 24/06/94 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Article : 12	Clause :	
Key words : declaration of conformity			
Question : Which purpose does the declaration of conformity of the manufacturer serve? Is it to be presented with each delivery of a PPE?			
Solution : The declaration of conformity has to be drawn up by the manufacturer to certify that the PPE placed on the market is in conformity with the directive; it is the basis for CE marking. The general opinion is that the declaration of conformity is to be issued by the manufacturer only once and has to be kept with the documentation of the manufacturer. This documentation has to be presented to the authorities on request.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement	(3) N° of CEN/TC (Secretary & Chairman)	(5) To be specified	
(2) HC = horizontal committee	(4) EEC Standing Committee 89/392		

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.002 Revision 03 Language : E	
Number of pages : 1	Date : 14/07/97	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 31/05/96 <input checked="" type="checkbox"/> Standing Committee..... 03/06/97	
Question related to : Directive 89/686/EEC Annex : III, 2	Article : EN/prEN : Clause :	Other :	
Key words : technical file, control and test facilities			
Question : Which minimal requirements are to be established for the control and test equipment of the manufacturer? Some notified bodies consider the verification of the manufacturer's control and test equipment a part of the type examination, others argue that this is not necessary, since article 10.4 (a) of the directive refers to the manufacturer's technical file, which according to annex III does not include the description of the control and test facilities.			
Solution : The requirements must be seen in connection with the technical file mentioned in the directive which must describe the control and testing. The notified body must be convinced that the system described is sufficient. The verification of the control and test equipment of the manufacturer is required only in relation to quality control according to article 11 B.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement	(3) N° of CEN/TC (Secretary & Chairman)	(5) To be specified	
(2) HC = horizontal committee	(4) EEC Standing Committee 89/392		




	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.005 Revision 03 Language : E
	Number of pages : 1	Date : 14/07/97	Approval by :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 31/05/96 <input checked="" type="checkbox"/> Standing Committee..... 03/06/97	
Question related to : Directive 89/686/EEC Annex :                                  Article : 10.2	EN/prEN : Clause :	Other :	
Key words : type examination certificate			
Question : Is it possible to issue certificates for one and the same product to different applicants (such as manufacturer and commission agent)?			
Solution : There can only be one type examination certificate for each single named product.  It was, however, acknowledged that several declarations of conformity can be issued on the basis of this type examination certificate.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			


	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.006 Revision 04 Language : E
	Number of pages : 1	Date : 15.12.2009	Approval by :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee ..... 31/05/96 <input checked="" type="checkbox"/> Standing Committee ..... 03/06/97	
Question related to :	EN/prEN :	Other :	
Annex :	Article :	Clause : [other]	
Key words : sub-contracting, accreditation, acceptance of test results, competence of laboratories			
Question : Is it possible for a certification body to accept test data obtained by other than accredited laboratories? Are test reports from authorities outside the Community acceptable for the purpose of CE marking? If this is so, what is the minimum criteria to be used in judging their competency and how should they be monitored? What quality control methods should be applied to sub-contracting laboratories? Can the notified body use test reports on materials, items or components carried out by other specialised laboratories? Can the notified body use reports on tests carried out by the manufacturer or the applicant?			
Solution : Under all circumstances, the notified body takes on the responsibility for test results/test reports it accepts as the basis for certification. Therefore, it should generally be recommended to use test results from accredited test laboratories only. As this will not always be possible, other sources of testing have to be used. Sub-contracting laboratories should meet the requirements according to ISO / IEC 17025, if this is not the case, the notified body has to ensure by other means that the test results are reliable. The notified body itself will have to specify the conditions for the acceptance of other test laboratories to carry out the tests. In all cases, a sub-contracting laboratory must satisfy condition (3) of Annex V of the directive. Quality control measures for sub-contracting test laboratories are important, the notified body itself is responsible for deciding how to proceed with this.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

(1) Essential safety requirement  
 (2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
 (4) EEC Standing Committee 89/392

(5) To be specified


	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.007 Revision 03 Language : E
	Number of pages : 1	Date : 14/07/97	Approval by :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 31/05/96 <input checked="" type="checkbox"/> Standing Committee..... 03/06/97	
Question related to : Directive 89/686/EEC Annex : Article : 10.5	EN/prEN : Clause : [other]	Other : 85/374/EEC	
Key words : retention, technical file, samples, liability			
Question : For how long must the EC type examination files, reference samples and tested items be stored?			
Solution : The directive specifies that the technical file will have to be held at the disposal of the authorities for 10 years following the placing on the market of the PPE. Some more information on the required retention of the technical file is given in EN 45 000. In addition, the specifications of the product liability directive (85/374/EEC) should be taken into consideration.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	


	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.008 Revision 02 Language : E
	Number of pages : 1	Date : 15.12.2009	Approval by :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee .....24/06/94 <input checked="" type="checkbox"/> Standing Committee .....01/07/96	
Question related to : Directive 89/686/EEC		EN/prEN :	Other :
Annex : II, 1.4	Article :	Clause :	
Key words : user information, availability			
Question : Questions have been raised concerning the user information to be supplied by the manufacturer, especially with regard to protective gloves. Some notified bodies seem to interpret the directive and EN 420 (protective gloves) to mean that it is sufficient, if the user information is available on request, whereas other notified bodies require the user information to be supplied with each item of PPE.			
Solution : The user information should be supplied with each item of PPE (the smallest commercial package available) as it is believed that this is the spirit of the directive and provides the information where and when it is most needed.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			


(1) Essential safety requirement  
 (2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
 (4) EEC Standing Committee 89/392

(5) To be specified

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.010 Revision 01 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 24/06/94 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Directive 89/686/EEC Annex : II, 1.4                      Article :	EN/prEN : Clause :	Other :	
Key words : user information, conformity assessment			
Question : Notified bodies that carry out certification procedures for foreign manufacturers have to decide what language version of the user information will be checked in the framework of conformity assessment.			
Solution : The notified body can choose which languages it does accept for testing. Any translation is the responsibility of the manufacturer / authorized representative. It would be useful, however, to note in the test report which language version was checked.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	


	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.011 Revision 01 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 24/06/94 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Directive 89/686/EEC Annex : III                      Article :	EN/prEN : Clause :	Other :	
Key words : technical file			
Question : What does the manufacturing technical file have to contain?			
Solution : A complete list of the information to be included in the technical file is laid down in annex III of the directive.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.012 Revision 04 Language : E
	Number of pages : 1	Date : 15.12.2009	Approval by :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee .....31/05/96 <input checked="" type="checkbox"/> Standing Committee .....03/06/97	
Question related to : Directive 89/686/EEC		EN/prEN :	Other :
Annex :	Article : 10.2	Clause :	
Key words : EC type examination, application			
Question : How can it be assured that the manufacturer has not presented the same file to two or even several notified bodies? How can it be assured that the manufacturer does not re-submit a file having been the subject of a previous EC type examination certificate refusal decision?			
Solution : The manufacturer will be asked for a written confirmation that he has not submitted the same file to another notified body and that the model presented for examination has not been the subject of any previous EC type certificate refusal decision.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

(1) Essential safety requirement  
 (2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
 (4) EEC Standing Committee 89/392


(5) To be specified

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.013 Revision 03 Language : E
	Number of pages : 1	Date : 15.12.2009	Approval by :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee .....31/05/96 <input checked="" type="checkbox"/> Standing Committee .....01/07/96	
Question related to : Directive 89/686/EEC		EN/prEN :	Other :
Annex :	Article : 10.5, 10.6	Clause :	
Key words : type examination certificate, withdrawal, extension, refusal			
Question : How should: - the EC type examination certificate - the withdrawal of an EC type examination certificate - an EC type certificate extension - an EC type examination certificate refusal be written?			
Solution : The general points to be included in the documents are laid down in the directive, the notified bodies being free to decide on the form of presentation.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

(1) Essential safety requirement  
 (2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
 (4) EEC Standing Committee 89/392


(5) To be specified


	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.014 Revision 02 Language : E
	Number of pages : 1	Date : 15.12.2009	Approval by :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee ..... 24/06/94 <input checked="" type="checkbox"/> Standing Committee ..... 01/07/96	
Question related to :	EN/prEN :	Other :	
Annex :	Article :	Clause : [other]	
Key words : certification, modified model			
Question : What is the procedure to be applied to the examination of variants of a PPE? Which criteria should be taken into account for the certificate?			
Solution : The notified body is free to decide whether it will grant extensions to existing certificates or it prefers issuing a new certificate for the variant to be certified. A PPE is considered as a variant of a reference PPE only if it differs on points which have no noticeable influence on the expected performances. The variants can correspond to differences relating in particular to dimensions, shape, nature of constituent materials, colour, assembly methods, manufacturing processes etc. It will be useful to consider in the vertical groups what criteria allow for acceptance of a modified model, e.g. modifications with regard to accessories, colours, types of glues, an additional size, etc. which do not change the essential functions of protection. It is the responsibility of the notified body to evaluate for each individual case if a given PPE can effectively be considered as a variant. In case of doubt, it will carry out any check, measurement or test considered to be useful. In every case and for each of the variants, the applicant will provide the notified body with a detailed description indicating the differences in comparison with the reference model and the number of examples of these variants required for complementary checks and tests.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

(1) Essential safety requirement  
 (2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
 (4) EEC Standing Committee 89/392

(5) To be specified

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.015 Revision 01 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 24/06/94 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Directive 89/686/EEC Annex : Article : 8.2	EN/prEN : Clause :	Other :	
Key words : limited series, individual items of PPE			
Question : What is the EC type examination procedure for limited series and PPE manufactured singly?			
Solution : In the logic of the EC directives, the model of the PPE (prototype) has to be submitted to an EC type examination before serial production starts.  exceptions: pre-prototypes and research prototypes			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.016 Revision 03 Language : E	
Number of pages : 1	Date : 14/07/97	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 31/05/96 <input checked="" type="checkbox"/> Standing Committee ..... 03/06/97	
Question related to : Directive 89/686/EEC Annex : Article : 10.4	EN/prEN : Clause :	Other :	
Key words : EC type examination procedure, harmonised standards			
Question : What is the procedure to be applied to the EC type examination in the absence of test methods provided by the appropriate harmonized European standards?			
Solution : The notified body has to decide what will be the basis for testing against the requirements of the directive. The manufacturer has to set the specification for the product and ask for certification against this specification. Under normal circumstances, the specifications of the manufacturer will remain strictly confidential. The notified body is responsible for assessing whether or not the specification meets the applicable requirements of annex II and determining whether or not the submitted PPE does comply with the requirements. It is recommended to refer to existing standards (national or ISO (international)) whenever possible. If this is not possible, the notified body should identify the objectives to be reached in testing for conformity with the requirements and specify test procedures appropriate for the EC type examination. The proposed method may be discussed with the notified bodies if this is necessary. If there is a general interest in a harmonization of the test procedure, the subject should be brought into the European standardization committee responsible.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	





**CO-ORDINATION OF NOTIFIED BODIES**  
**PPE-Directive 89/686/EEC + amendments**  
**RECOMMENDATION FOR USE**


CNB/P/00.017  
Revision 01  
Language : E


Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group.....	
		<input checked="" type="checkbox"/> Horizontal Committee..... 24/06/94	
		<input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to :	EN/prEN :	Other :	
Annex :	Article :	Clause :	
Key words : test reports			
Question : presentation of test reports			
Solution : It was generally agreed that no harmonized format is necessary for the presentation of test reports.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement	(3) N° of CEN/TC (Secretary & Chairman)	(5) To be specified	
(2) HC = horizontal committee	(4) EEC Standing Committee 89/392		





	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.019 Revision 01 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 24/06/94 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Directive 89/686/EEC Annex : II, 1.4                      Article :	EN/prEN : Clause :	Other :	
Key words : user information			
Question : On which point should the verification on the information/instruction notice provided by the certificate applicant be focused?			
Solution : Within the EC type examination framework, the notified body ensures that the information/instruction notice from the manufacturer or applicant covers all the items of article 1.4 of annex II of directive 89/686/EEC modified and that it is presented in an accurate and understandable way.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	


	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.020 Revision 01 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 24/06/94 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Annex :                      Article :	EN/prEN : Clause :	Other :	
Key words : testing of materials			
Question : Is it permissible to carry out tests on materials, parts or components identical to those comprising the PPE instead of carrying out tests on the PPE itself? If so, what are the conditions to be met for type approval and for production control?			
Solution : It is possible to carry out tests on materials described in the standards with the sample taken either on the PPE itself or on a sample of the material if the manufacturer attests (in writing) that it is strictly identical to that used in the construction to the PPE and if the notified body can confirm the identity by examination of the reference PPE and the samples supplied. This procedure should be limited to a specific case as, for example, when referring to high cost PPE produced in small quantities. The applicant has to supply one example of the PPE submitted to EC type examination so that the notified body can check that the materials or items put forward for testing are indeed identical to those composing the PPE.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.021 Revision 01 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 24/06/94 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Annex :                      Article :	EN/prEN : Clause :	Other :	
Key words : type examination certificate, modification of products			
Question : What should the manufacturer or his authorized representative established in the Community do in the case of a modification to a PPE model having been the subject of an EC type examination certificate?			
Solution : The directive does not explicitly provide for the case of modification of a PPE model having been the subject of an EC type examination certificate. The manufacturer or his authorized representative established in the Community has to inform the notified body that delivered the EC type examination certificate of any intended modification of the PPE. The notified body then has to decide whether the modification does or does not require new type examination procedures.  If the modification only involves minor changes not affecting the safety characteristics of the product, the notified body informs the applicant that the EC type examination certificate will continue to be valid for the modified mode. It may then either deliver a type examination certificate extension or a new certificate. If the modification consists of major changes to the product, the notified body has to inform the manufacturer or the authorized representative that the certificate cannot be transferred to the modified model. If the manufacturer intends to keep the modifications, he will be required to make a new official request for an EC type examination.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	


	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.022 Revision 01 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 24/06/94 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Annex :	Article : EN/prEN : Clause :	Other :	
Key words : identification of test samples			
Question : What are the measures to be taken for the identification of tested models for any subsequent controlling inspection or expertises?			
Solution : There must be no ambiguity regarding the identification of the PPE having been submitted as a type (model) to a notified body for EC type examination. PPE placed on the market are the subject of the tested type declaration of conformity.  The following is recommended: <ul style="list-style-type: none"> <li>- the alphanumeric reference of the models must be provided by the manufacturer with an indication of its meeting</li> <li>- the photographs needed for correct identification of the PPE must accompany the certificate and a copy of these photographs must be archived with the file by the notified body</li> <li>- an example of the PPE in a finished state can be archived by the notified body when this is possible</li> <li>- if this is not possible, representative samples will have to be stored.</li> </ul>			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	


	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.023 Revision 02 Language : E	
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Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 31/05/96 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Directive 89/686/EEC Annex : Article : 11 A.1	EN/prEN : Clause :	Other :	
Key words : quality control, manufacturer			
Question : Article 11 A of the directive refers to "a manufacturer", but who is "a manufacturer"?			
Solution : Agreement that the manufacturer in this context must at least carry out the final assembly of the PPE. This is necessary due to the responsibility to ensure homogeneity of production, which can only be achieved through controlling the manufacturing process.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.024 Revision 02 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 31/05/96 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Directive 89/686/EEC Annex : Article : 11 A.2	EN/prEN : Clause :	Other :	
Key words : quality control, checks			
Question : At what frequency should the required "necessary checks" (as referred to in article 11 A) be carried out?			
Solution : A minimum of one per year, the year starting from the date of issue of the certificate.			
Sent for information to <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.025 Revision 02 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 31/05/96 <input checked="" type="checkbox"/> Standing Committee ..... 01/07/96	
Question related to : Directive 89/686/EEC Annex :    Article : 11 A.2	EN/prEN : Clause :	Other :	
Key words : quality control, application of CE marking			
Question : Should the checks referred to in article 11 A.2 be carried out before the application of the CE marking or afterwards?			
Solution : As a minimum the manufacturer must have entered into a formal agreement with a notified body for assessment against 11 A. This is explicit in article 12 of the directive, whereby the EC declaration is drawn up before the application of the CE marking and part of the declaration states which body is/will be supervising the 11 A procedure. The amending directive covering the application of the CE marking requires the number of the notified body responsible for administering article 11 to be added to the marking. It would appear sensible for notified bodies to have checked a company's control procedure before agreeing to its number being marked on the product.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	




	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.029 Revision 01 Language : E	
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Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 24/06/94 <input checked="" type="checkbox"/> Standing Committee..... 20/05/95	
Question related to :	EN/prEN :	Other :	
Annex :	Article :	Clause :	
Key words : CE marking, categories			
Question : CE marking according to the directive 93/68/EEC does not provide for a clear distinction between categories I and II. Is it possible to amend the provisions on CE marking so as to include a distinction, as this is considered to be helpful to the user?			
Solution : At the moment there is no intention to change the situation by another amending text.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	


	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.030 Revision 04 Language : E
	Number of pages : 1	Date : 15.12.2009	Approval by :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee ..... 27/05/98 <input checked="" type="checkbox"/> Standing Committee ..... 20/04/98	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Article : 11 A.2	Clause :	
Key words : article 11 A , necessary checks			
Question : What are the necessary checks required under article 11 A.2?			
Solution : <u>Each certified model</u> to be selected by the notified body at least once per year. The notified body has an obligation to sample and test products that adequately represent the products within the family / group of products. The selected sample(s) must be checked for compliance with the type described in the EC type approval certificate and the relevant basic requirements of the directive. That means, the compliance with 11 A is checked by every model tested once a year, no assessment of the manufacturing process.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

(1) Essential safety requirement  
 (2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
 (4) EEC Standing Committee 89/392

(5) To be specified

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.031 Revision 01 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 02/06/95 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Directive 89/686/EEC Annex : Article : 11 A, 11 B	EN/prEN : Clause :	Other :	
Key words : article 11 A and B, withdrawal of certificates			
Question : What procedure should be followed in the event of failures during 11 A and 11 B examinations?			
Solution : In the event of failures in 11 A and 11 B examinations, the notified body concerned has to decide in each individual case, taking into account the reasons that lead to the failure and the risks involved. In serious cases (danger of life) the notified body should proceed to withdraw the certificate; in that case the Member State giving notification will have to be informed.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.032 Revision 01 Language : E	
Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 02/06/95 <input checked="" type="checkbox"/> Standing Committee..... 01/07/96	
Question related to : Annex :                      Article :	EN/prEN : Clause :	Other :	
Key words : manufacturer, authorized representative			
Question : The directive always refers to the manufacturer or his authorized representative established in the Community. Can manufacturers worldwide act equivalent to companies in the Community?			
Solution : The PPE group of the Standing Committee 89/392/EEC stated that the directive 89/686/EEC does not distinguish between the manufacturer's location inside or outside the EEA. Only (authorized) representatives need to be based in the EEA.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.033  
Revision 03  
Language : E


RECOMMENDATION FOR USE

Number of pages : 1	Date : 29/03/99	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group .....	
		<input checked="" type="checkbox"/> Horizontal Committee.....	
		<input checked="" type="checkbox"/> Standing Committee.....	24/11/98
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Article :	Clause :	
Key words : category I or II for chemical protective gloves			
Question : Under which circumstances can gloves protecting against chemicals be classified as category II or even I?			
Recommended solution : Gloves for protection against chemicals can be in category II only if: - the protection is unlimited during the recommended lifetime of the product - the gloves are provided with an exclusive list of chemicals for which protection is given In all other cases, they are category III, unless they meet article 8.3 when they are category I. The gloves shall always be accompanied by instructions for use. These instructions shall be checked by the notified bodies.			
Sent for information to : <input checked="" type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

(1) Essential safety requirement  
(2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392


(5) To be specified


	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.034 Revision 02 Language : E
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Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee..... 01/06/95 <input checked="" type="checkbox"/> Standing Committee..... 18/11/97	
Question related to : Directive 89/686/EEC Annex : III                      Article : 10	EN/prEN : Clause :	Other :	
Key words : type examination: contents of technical file, technical documentation			
Question : Which documents are part of the technical file / technical documentation mentioned in the directive? Annex III of the directive makes a distinction between the technical documentation, which has to be maintained by the manufacturer for submission to the authorities, if need be, and the technical file, which has to be submitted to the notified body in the framework of type examination. The description of the control and test facilities and the instructions of the manufacturer are part of the technical documentation, but not of the technical file. This means, however, that it is not possible for the notified body to assess the suitability of the test facilities or of the instructions of use during type examination.			
Recommended solution : It should be noted that there is no on-site assessment of the test equipment of the manufacturer under article 10 procedures. However, the description of the test equipment as well as the instructions for use are important for the assessment of the conformity of a product with the directive. Therefore, they have to be considered to be a part of the technical file.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			


(1) Essential safety requirement  
 (2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
 (4) EEC Standing Committee 89/392

(5) To be specified

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.036 Revision 03 Language : E	
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Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 27/05/98 <input checked="" type="checkbox"/> Standing Committee..... 20/04/98	
Question related to : Directive 89/686/EEC Annex : II; 1.4 (e)                      Article :	EN/prEN : Clause :	Other :	
Key words : period of obsolescence			
Question : There are a few items of PPE for which a definitive life can be stated. In general, the time for which an item of PPE can be used is dependent upon many and varied effects; for example storage, maintenance, conditions and frequency of use, etc. This presents a problem for manufacturers required to state a period and for notified bodies in assessing whether or not this requirement is complied with. A practical solution is required which satisfies the spirit of the Directive and supplies the necessary information to the user.			
Recommended solution : All relevant information on the period of obsolescence and/or instructions to enable the user to assess and inspect the item to determine whether or not the item can continue to be used. Individual vertical groups may define more detailed specifications for different types of PPE. (see annex II, 2.4)			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.038 Revision 03 Language : E
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Origin : Horizontal Committee		<input type="checkbox"/> ..... <input checked="" type="checkbox"/> Horizontal Committee..... 27/05/98 <input checked="" type="checkbox"/> Standing Committee..... 20/04/98	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Clause :		
Key words : components from different manufacturers			
Question : Should a notified body agree to issue an EC Type Examination for a product submitted by manufacturer "A" which includes interchangeable components produced by a manufacturer "B" where the product requires to be tested as a complete device? for example: a) filters for an air powered device b) chemical protective clothing without a hood and/or boots c) helmet mounted ear muffs			
Recommended solution : A notified body is responsible for reviewing the Technical Documentation for compliance with the relevant requirements of the Directive. Provided the client's documentation submitted covers all the applicable requirements the notified body may perform or arrange for the necessary tests to be carried out and if found satisfactory issue an EC Type Examination Certificate. Note: It is the manufacturer "A"'s responsibility to monitor that each subsequent product is in conformance with that tested for the EC Type Examination and that the product manufactured by "B" remains the same and compatible with his tested product.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.046 Revision 04 Language : E	
Number of pages : 1	Date : 31/05/99	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> ..... <input checked="" type="checkbox"/> Horizontal Committee..... 26/05/99 <input checked="" type="checkbox"/> Standing Committee ..... 21/06/99	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Clause :		
Key words : marking, standard reference, testing according to prEN			
Question : If only a prEN is available at the time of EC type approval, can the product be marked with the standard number „EN ...“? Where the EC type examination is issued against a prEN, can EN be marked on the product, once the standard is ratified?			
Recommended solution : Marking with a standard reference is not mandatory by the directive.  Where a manufacturer decides to mark a standard or prEN on his product, the following principles apply: As long as no final standard exists or the final standard is not identical with the prEN, the marking cannot be "EN ...". If the ratified EN is identical to the prEN, then „EN ...“ may be marked on the product. Where the ratified EN is not identical to the prEN, then „EN ...“ cannot be marked on the product. Marking with a prEN is not recommended. However, where a manufacturer decides to mark with the prEN used for the EC type examination then it should be fully identified by year and/or issue.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement	(3) N° of CEN/TC (Secretary & Chairman)	(5) To be specified	
(2) HC = horizontal committee	(4) EEC Standing Committee 89/392		





**CO-ORDINATION OF NOTIFIED BODIES**  
**PPE-Directive 89/686/EEC + amendments**

CNB/P/00.051  
 Revision 04  
 Language: E


**RECOMMENDATION FOR USE**


Number of pages: 1		Date: 04.09.02		Approval by :		Approved on :	
Origin : Horizontal Committee				<input type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee <input checked="" type="checkbox"/> Standing Committee		..... 23.02.00..... 15.01.02.....	
Question related to: Directive 89/686/EEC				EN/prEN:		Other:	
Annex: II, 1.4		Article:		----- Clause:			
Key words: use of pictograms							
Question: Is it possible to mark a product with a pictogram described in an EN standard when the verification of essential requirements has been made against another EN standard or other technical specification ?							
Solution: It is possible to use the pictogram even if the standard used is not the EN standard where the pictogram is described. The notified body, in reviewing the manufacturer's instructions for use (information supplied by the manufacturer), must ensure that the meaning of the pictogram is clearly defined in respect of the essential health and safety requirements of the directive. NOTE: 'Pictogram' refers to the pictorial presentation; this does not include the EN number or performance levels. These must not be used if the EN is not the basis for testing.							
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input type="checkbox"/> SC (4) <input type="checkbox"/> other (5)							
(3):				(5):			


(1) Essential safety requirement  
 (2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
 (4) EEC Standing Committee 89/392

(5) To be specified

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.052 Revision 03 Language : E	
Number of pages : 1	Date : 27/08/98	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> ..... <input checked="" type="checkbox"/> Horizontal Committee..... 04/06/97 <input checked="" type="checkbox"/> Standing Committee ..... 20/04/98	
Question related to :	EN/prEN :	Other :	
Annex :	Article :	Clause :	
Key words : test reports, designation of materials			
Question : In test reports, materials are often only referred to by a single, mostly commercial reference name. In many cases, however, this name covers a variety of materials different by structure and weight (for fabrics) or by origin and thickness (for leather). Is it possible to have a uniform and clear "finger print designation" of materials in test reports in order to make an evaluation easier? For this purpose, we propose to use the elements as given below: - aramid twill 2/1 - 270 g/m <sup>2</sup>			
Recommended solution : A unique reference number or name identifying the material must be the same in the technical file and in the test report. The technical file should contain a documentation of the material, i. e. a sample or a proper identification.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(1) Essential safety requirement (2) HC = horizontal committee	(3) N° of CEN/TC (Secretary & Chairman) (4) EEC Standing Committee 89/392	(5) To be specified	

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.058 Revision 03 Language : E	
Number of pages : 1	Date : 27/08/98	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> ..... <input checked="" type="checkbox"/> Horizontal Committee..... 04/06/97 <input checked="" type="checkbox"/> Standing Committee..... 20/04/98	
Question related to : Annex :                      Article :	EN/prEN : Clause :	Other :	
Key words : test reports, materials			
Question : How old can test reports be when they are used for type examination?			
Recommended solution : This is the responsibility of the notified body. The general view is that there should be no time limit for previous tests.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
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	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.061 Revision 03 Language : E	
Number of pages : 1	Date : 15/01/98	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> ..... <input type="checkbox"/> ..... <input checked="" type="checkbox"/> Standing Committee ..... 18/11/97	
Question related to :	EN/prEN :	Other :	
Annex :	Article :	Clause :	
Key words : slip resistance, type examination certificate			
Question : Does slip resistance have to be considered an essential requirement for safety, protective and occupational footwear?			
Recommended solution : Slip resistance is a general feature of safety, protective and occupational footwear. Notified bodies have to carry out slip resistance testing, unless the manufacturer clearly claims in his product specification and in the user information that the footwear does not meet this requirement.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
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CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.067  
Revision 02  
Language : E


RECOMMENDATION FOR USE

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		<input checked="" type="checkbox"/> Standing Committee..... 29/11/99	
Question related to :	EN/prEN :	Other :	
Annex :	Article :	Clause :	
Key words :			
EC declaration of conformity			
Question :			
Different interpretations seem to be possible with regard to the declaration of conformity:			
1.) The declaration is issued by the manufacturer when he places the product on the market for the first time.			
2.) The declaration is issued by the manufacturer for every individual product identified by a unique serial number when placed on the market.			
Recommended solution :			
The first option should be agreed.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

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	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.068 Revision 05 Language : E
	Number of pages : 1	Date : 15.12.2009	Approval by :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee .....26/05/99 <input checked="" type="checkbox"/> Standing Committee .....21/06/99	
Question related to : Directive 89/686/EEC		EN/prEN :	Other :
Annex :	Article :	Clause :	
Key words : revision of standard, validity, EC type examination certificate			
Question : When a new version of an EN standard is published, are manufacturers obliged to get their products tested to the new/revised version or can they continue to sell their product(s)?			
Recommended solution : Current certificates remain valid. However, manufacturers have a responsibility to keep abreast of changes and to modify their products in the light of these changes to continue to supply safe products, which may necessitate the issue of a new certificate.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

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	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.075 Revision 04 Language : E	
Number of pages : 1	Date : 27/08/98	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> ..... <input checked="" type="checkbox"/> Horizontal Committee..... 04/06/97 <input checked="" type="checkbox"/> Standing Committee..... 20/04/98	
Question related to : Directive 89/686/EEC Annex : Article : 10.2, 11 A, 11 B	EN/prEN : Clause :	Other :	
Key words : distribution, type examination certificate			
Question : How should files concerning PPE likely to have several product identifications be processed?			
Recommended solution : There are two acceptable situations.  <b>1) The original manufacturer or his authorised representative remains responsible for placing the equipment on the market</b> The manufacturer is the certificate holder, and established the declarations of conformity. The technical construction file indicates the different forms of product identification and markings as well as the trade name of the distributors. The various versions of the instruction handbook are subject to EC type-examination (with the exception of direct translations into foreign languages).  <b>2) The distributor or importer, acting as a manufacturer, is responsible for placing the equipment on the market</b> Being responsible for placing the equipment on the market, the distributor / importer must request an EC type examination. The certificate or the extension to the certificate is established in the trade name of whoever is responsible for placing the equipment on the market. He, in turn, established the declarations of conformity in his name.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
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	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.080 Revision 02 Language : E	
Number of pages : 1	Date : 15/01/98	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> ..... <input checked="" type="checkbox"/> Horizontal Committee..... <input checked="" type="checkbox"/> Standing Committee..... 18/11/97	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Clause :		
Key words : Production Plant			
Question : Do certificates only cover PPE made at the production plant(s) specified either on the certificate or associated documents? If no, is the certificate holder free to sub-contract production to any alternative plant, without reference to the Notified Body, and apply the CE marking on the basis of the original certificate and declaration?			
Recommended solution : The Type Examination certificate is linked directly to the production plant(s) specified at the time of application. <ul style="list-style-type: none"> <li>- Only products made at the specified site(s) are covered by the certificate and these can be CE marked following the drawing up of the necessary declaration.</li> <li>- If alternative production plants are to be used, the Notified Body who issued the original certification must be informed. The N.B. decides, in agreement with the manufacturer, what level of verification testing, if any, is required before amending the certificate and/or the technical file.</li> </ul>			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
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	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.081 Revision 03 Language : E	
Number of pages : 1	Date : 31/05/99	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> ..... <input checked="" type="checkbox"/> Horizontal Committee..... 27/05/98 <input checked="" type="checkbox"/> Standing Committee..... 21/06/99	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Clause :		
Key words : interchangeable components, EC type examination			
Question : Should interchangeable components be submitted to an EC type examination?			
Recommended solution : Yes, an EC type examination certificate can be issued in accordance with Article 1;2 c. The notified body shall carry out sufficient evaluation and/or testing to verify their suitability for the stated equipment in its final assembly.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
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	<p>CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments</p> <p>RECOMMENDATION FOR USE</p>	<p>CNB/P/00.087 Revision 05 Language: E</p>
Number of pages: 1	Date: 12.07.2005	Approval by : <span style="float: right;">Approved on :</span>
Origin : Article 11 A/B ad hoc committee		<input checked="" type="checkbox"/> Vertical Group <span style="float: right;">.01.12.2004.....</span> <input checked="" type="checkbox"/> Horizontal Committee <span style="float: right;">.03.12.2004.....</span> <input checked="" type="checkbox"/> Standing Committee <span style="float: right;">.30.06.2005.....</span>
Question related to:	EN/prEN:	Other:
Annex:	Article:	----- Clause:
<p>Key words:</p> <p>quality assurance system</p>		
<p>Question:</p> <p>Must existing certificates relating to QA-Systems (ISO 9001:2000) be accepted by a notified body?</p>		
<p>Solution:</p> <p>No; but the notified body is able to take into account existing certificates relating to QA-systems (ISO 9001:2000) if it is convinced of the qualification of the certification body (accreditation, mutual recognition and others). In all cases the notified body must add product and regulation-related aspects.</p>		
<p>Sent for information to:    <input type="checkbox"/> members of the VG    <input type="checkbox"/> other(s) VG    <input checked="" type="checkbox"/> HC (2)    <input type="checkbox"/> TC (3)    <input checked="" type="checkbox"/> SC (4)    <input type="checkbox"/> other (5)</p> <p style="text-align: center;">(3): <span style="margin-left: 200px;">(5):</span></p>		

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	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.088 Revision 04 Language : E
	Number of pages : 1	Date : 15.12.2009	Approval by :
Origin : VG12 Certification of Quality Systems, article 11B HC ad-hoc committee		<input checked="" type="checkbox"/> Vertical Group .....29/11/95 <input checked="" type="checkbox"/> Horizontal Committee .....05/01/98 <input checked="" type="checkbox"/> Standing Committee .....20/04/98	
Question related to : Directive 89/686/EEC		EN/prEN :	Other :
Annex :	Article : 11.B (2)	Clause :	
Key words : Quality Assurance System, Supervision, Frequency of Audits			
Question : What frequency of audits is necessary to fulfil the obligation arising from Article 11 B (2) of Directive 89/686/EEC?			
Recommended solution : A supervision frequency of at least once a year.  See also RfU no. 00.106.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			


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	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.089 Revision 03 Language : E	
Number of pages : 1	Date : 27/08/98	Approval by :	Approved on :
Origin : VG12 Certification of Quality Systems, article 11B HC ad-hoc committee		<input checked="" type="checkbox"/> Vertical Group..... 29/11/95 <input checked="" type="checkbox"/> Horizontal Committee..... 05/01/98 <input checked="" type="checkbox"/> Standing Committee..... 20/04/98	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Clause :		
Key words :			
Question : When must ISO 9001/2/3: 1994 be used as the harmonised standard?			
Recommended solution : The certification and procedures, of notified bodies and manufacturers, which reference ISO 9001/2/3, must reference the 1994 version by the end of 1998, at the latest.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
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Number of pages : 1	Date : 27/08/98	Approval by :	Approved on :
Origin : VG12 Certification of Quality Systems, article 11B HC ad-hoc committee		<input checked="" type="checkbox"/> Vertical Group..... 29/11/95 <input checked="" type="checkbox"/> Horizontal Committee..... 05/01/98 <input checked="" type="checkbox"/> Standing Committee..... 20/04/98	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Article : 11.B (b) / 11.A.3	Clause :	
Key words :			
Question : Must the "appropriate tests" be as specified in the product standard or product specification?			
Recommended solution : The manufacturer's routine/regular inspections and tests can be alternatives, providing that the manufacturer can prove there is sufficient correlation. Where this is the case, the test/inspection programme against the product standard/specification can be less frequent.			
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	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.092 Revision 02 Language : E	
Number of pages : 1	Date : 31/05/99	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 26/05/99 <input checked="" type="checkbox"/> Standing Committee..... 21/06/99	
Question related to : Directive 89/686/EEC Annex : II                      Article : 1.4 (i)	EN/prEN : Clause :	Other :	
Key words : notified body reference, information supplied by the manufacturer			
Question : 1. Has information on the notified body who certifies a PPE product to be included in the user information? 2. What is the correct interpretation of the PPE Directive as amended?			
Recommended solution : 1. Yes. Reference 93/68/EEC (Article 7, para. 7) which amends section 1.4 requiring „the name, address and identification number of the notified body involved in the design stage of the PPE;“ 2. The details to be included in the manufacturer’s user information must be that of the notified body responsible for the issue of the EC type examination.  It should be noted that in some cases more than one notified body may be involved, i. e. combined PPE. In such cases the information supplied would be for each notified body involved.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
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Number of pages : 1	Date : 31/05/99	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 27/05/98 <input checked="" type="checkbox"/> Standing Committee..... 21/06/99	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Article :	Clause :	
Key words : Element, CE marking			
Question : May an element (e. g. attachment element, steel toe cap) which is not sold to the end user be CE marked?			
Recommended solution : No, these elements are items that are supplied to a manufacturer for the manufacture of PPE. Note: Certain items may be CE marked under another directive.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
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Number of pages : 1	Date : 31/05/99	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group..... <input checked="" type="checkbox"/> Horizontal Committee..... 27/05/98 <input checked="" type="checkbox"/> Standing Committee..... 21/06/99	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Article :	Clause :	
Key words : harmonised standards, essential requirements, EC type examination			
Question : When carrying out an EC type examination, what is the responsibility of the notified body when the applicable product harmonised standard does not address all the relevant Health and Safety Requirements?			
Recommended solution : Where a relevant product harmonised standard does not address all the relevant Health and Safety Requirements the manufacturer must identify those not addressed in the standard and also state how these are dealt with in his Technical File. The notified body is responsible for confirming that all the relevant Health and Safety Requirements have been identified, listed and adequately dealt with when carrying out their review, inspection and testing for the EC Type Examination. Note 1: A product harmonised standard gives a presumption of conformity with those Basic Health and Safety Requirements which it identifies for the product and addresses. Note 2: It must be remembered that the Directive is the law and must be complied with whilst standards are one means by which a manufacturer may demonstrate his compliance with the Directive's requirements.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
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Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee..... 26/05/99 <input checked="" type="checkbox"/> Standing Committee..... 29/11/99	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Article : 10, 4 (b)	Clause :	
Key words : technical file			
Question : How should the inspection body „verify“ that the model is the product described in the manufacturer's technical file?			
Solution : The inspection body is seen as the notified body in terms of the directive. The generally accepted action in order to verify that a PPE model has been produced in accordance with the manufacturer's technical file is to conduct a visual comparison between an example of the model and a description of the model. The objective of the comparison is to ensure that, in general terms, the product is as described and that there are no obvious differences in general form or materials.  Note: The description of the model may take various forms, e. g. general assembly drawings, component drawings, photographs, material descriptions, etc.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

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CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.096  
Revision 06  
Language: E

RECOMMENDATION FOR USE

Number of pages: 1	Date: 04.09.02	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group	.....
		<input checked="" type="checkbox"/> Horizontal Committee	04.07.01.....
		<input checked="" type="checkbox"/> Standing Committee	15.01.02.....
Question related to: Directive 89/686/EEC	EN/prEN:	Other:	
Annex: II, 1.2.1.1	Article:	-----	
Key words:			
innocuousness of PPE			
Question:			
What should notified bodies require from the manufacturer to demonstrate compliance with annex II, 1.2.1.1 ?			
Solution:			
Compliance may be demonstrated by a written declaration confirming that the submitted PPE does not contain any substances at levels that are known to, or suspected to, adversely affect user hygiene or health, if present; a list of these substances has to be submitted as part of the technical file. Tests as required by harmonised standards will not be affected.			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
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CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.098  
Revision 03  
Language: E

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Number of pages: 1	Date: 04.09.02	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group	.....
		<input checked="" type="checkbox"/> Horizontal Committee	23.02.00.....
		<input checked="" type="checkbox"/> Standing Committee	15.01.02.....
Question related to: Directive 89/686/EEC	EN/prEN:	Other:	
Annex: Article: 10	Clause:	-----	
Key words: conformity to standard			
Question: Is it possible to certify a product in compliance with a standard where one or more requirements of the standard are not satisfied?			
Solution: No. NOTE: The product may be certified in compliance with the essential health and safety requirements of the directive.			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(3):		(5):	

(1) Essential safety requirement  
(2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.099  
Revision 02  
Language : E

RECOMMENDATION FOR USE

Number of pages : 1	Date : 11/12/99	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group .....	<input checked="" type="checkbox"/> Horizontal Committee..... 27/05/99
		<input checked="" type="checkbox"/> Standing Committee..... 29/11/99	
Question related to : Directive 89/686/EEC	EN/prEN :	Other :	
Annex :	Article :	Clause :	
Key words : CE marking, separate items of PPE, technical file			
Question : The manufacturer produces a range of products that can be used individually and in combination. 1. Is it possible to submit one technical file containing the designs etc. for all of these products? 2. In such a case, can each product separately bear the CE marking?			
Recommended solution : 1. It is possible to submit one technical file only for all products. 2. Yes, each product must be CE marked.			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

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(2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.104  
Revision 02  
Language: E

RECOMMENDATION FOR USE

Number of pages: 1	Date: 04.09.02	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group	.....
		<input checked="" type="checkbox"/> Horizontal Committee	23.02.00.....
		<input checked="" type="checkbox"/> Standing Committee	15.01.02.....
Question related to: Directive 89/686/EEC	EN/prEN:	Other:	
Annex:	Article: 8.4a	-----	
Clause:			
Key words: category; certification			
Question: How should the word 'emergency' in the English language version of the Directive be understood?			
Solution: It should be understood as in the original French version, which says 'intervention'.			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(3):		(5):	

(1) Essential safety requirement  
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(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.105  
Revision 02  
Language: E

RECOMMENDATION FOR USE

Number of pages: 1	Date: 04.09.02	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group	.....
		<input checked="" type="checkbox"/> Horizontal Committee	27.10.00.....
		<input checked="" type="checkbox"/> Standing Committee	15.01.02.....
Question related to: Directive 89/686/EEC	EN/prEN:	Other:	
Annex: Article: 11A	Clause:	-----	
Key words: witnessed testing			
Question: Is it acceptable for witnessed testing to be performed by the manufacturer/importer etc. in support of 11.A monitoring ?			
Solution: The preferred method is to have testing carried out by an independent laboratory. However, in exceptional circumstances it is acceptable, but it must be under the full responsibility of the notified body and shall be witnessed by an independent representative who has knowledge of the product and test methods.			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(3):		(5):	

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(4) EEC Standing Committee 89/392

(5) To be specified





CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

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RECOMMENDATION FOR USE

Number of pages: 1	Date: 04.09.02	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group	.....
		<input checked="" type="checkbox"/> Horizontal Committee	27.10.00.....
		<input checked="" type="checkbox"/> Standing Committee	15.01.02.....
Question related to: Directive 89/686/EEC	EN/prEN:	Other:	
Annex:	Article: 11.A.3	-----	
Clause:			
Key words: sample selection			
Question: What is the minimum requirement(s) to be applied to the method of obtaining samples for testing under Article 11.A ?			
Solution: As a minimum, the notified body or an independent representative of the notified body, shall visit a location agreed with the certificate holder (manufacturing site, importer, distributor, retail outlet), and shall randomly select the samples from the available stock.			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(3):		(5):	

(1) Essential safety requirement  
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(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments  RECOMMENDATION FOR USE		CNB/P/00.109 Revision 03 Language : E
	Number of pages : 1	Date : 26.10.06	Approval by :
Origin : Article 11 A/B ad hoc group		<input type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee ..... <input checked="" type="checkbox"/> Standing Committee .....	05.05.06 31.07.06
Question related to : Directive 89/686/EEC		EN/prEN :	Other :
Annex :	Article : 11.A	Clause :	
Key words : 11.A test clauses			
Question : When an EC Type Examination is based upon a withdrawn standard, should the 11.A testing be conducted against the withdrawn standard or the current version ?			
Recommended solution : Whilst the type examination certificate remains valid, the 11.A testing should be against the edition of the standard used as a basis to demonstrate conformity with the Directive.  (Cross reference sheet 00.068 concerning the validity of Type Examination Certificates.)			
Sent for information to : <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

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(3) N° of CEN/TC (Secretary & Chairman)  
 (4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.113

Revision 03

Language: E

RECOMMENDATION FOR USE

Number of pages: 1		Date: 15.12.2009	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee <input checked="" type="checkbox"/> Standing Committee		
Question related to: Directive 89/686/EEC		EN/prEN:	Other:	
Annex: III	Article: 10	----- Clause:		
Key words: Test and Inspection of Production				
Question: How is the phrase 'control AND test facilities' in annex III, 2 to be understood?				
Solution: As a minimum, the system described should include a summary of how often the manufacturer will carry out the inspections and tests required by the standard or specification, e.g. batch tests, annual tests, receiving inspections etc. The system should clearly show that the manufacturer checks and confirms continuing compliance against all applicable requirements over a stated period / frequency and uniformity with the tested type (which must be assessed as satisfactory by the notified body). See also RfU 00.002.				
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)				
(3):		(5):		

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(4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

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Revision 03  
Language: E

RECOMMENDATION FOR USE

Number of pages: 1	Date: 22.08.03	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group	.....
		<input checked="" type="checkbox"/> Horizontal Committee	05.09.02.....
		<input checked="" type="checkbox"/> Standing Committee	11.06.03.....
Question related to: Directive 89/686/EEC	EN/prEN:	Other:	
Annex: Article: 8.4, 11.A, 11.B	Clause:	-----	
Key words: manufacturer			
Question: There are various references in the Directive to a 'Manufacturer', but what is the accepted definition of a manufacturer?			
Solution: According to the Blue Book, the Manufacturer to has to be defined as			
<ul style="list-style-type: none"><li>- any natural or legal person who takes responsibility for designing and manufacturing a PPE with a view to placing it on the Community market under his own name;</li><li>- any natural or legal person who assembles, packs, processes or labels ready-made products with a view to their being placed on the Community market under his own name;</li><li>- any natural or legal person who changes the intended use of a product in such a way that different essential requirements will become applicable;</li><li>- any natural or legal person who customises, modifies or rebuilds a PPE.</li></ul>			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(3):		(5):	

(1) Essential safety requirement  
(2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

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Revision 02  
Language: E

RECOMMENDATION FOR USE

Number of pages: 1	Date: 22.08.03	Approval by :	Approved on :
Origin : Horizontal Committee		<input checked="" type="checkbox"/> Vertical Group 5	..11.04.02.....
		<input checked="" type="checkbox"/> Horizontal Committee	..05.09.02.....
		<input checked="" type="checkbox"/> Standing Committee	..11.06.03.....
Question related to: Directive 89/686/EEC	EN/prEN:	Other:	
Annex: II, 1.2.1.1	Article:	-----	
Key words: information supplied by the manufacturer; sensitising or allergenic substances			
Question: Should the manufacturer of PPE display all substances with sensitising or allergenic potential in the "information supplied by the manufacturer", if the PPE is designed to get (even if only partly) in close skin contact with the user, or if parts of the PPE may be released and taken up via the inhalation route by the user?			
Solution: Yes. The PPE directive 89/686/EEC, annex II, 1.2.1.1 (suitable constituent materials) requires that "PPE materials and parts, including any of their decomposition products must not adversely affect user hygiene or health". In case that PPE contains substances which are known to be potentially sensitising or allergenic, the manufacturer has to display each individual relevant substance in the information supplied by the manufacturer to give a warning to all potentially concerned users.			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(3):		(5):	

(1) Essential safety requirement  
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(4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.118  
Revision 02  
Language: E

RECOMMENDATION FOR USE

Number of pages: 1	Date: 22.08.03	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group	.....
		<input checked="" type="checkbox"/> Horizontal Committee	05.09.02.....
		<input checked="" type="checkbox"/> Standing Committee	11.06.03.....
Question related to: Directive 89/686/EEC	EN/prEN:	Other:	
Annex: Article: 8	Clause:	-----	
Key words: categorisation; welding			
Question: 1. Does welders' PPE have to offer protection against "electrical risks" in the aim of the directive (article 8.4 a), line 7) ? 2. What is the category of welders' PPE?			
Solution: 1. No. 2. Welders' PPE are in category II.			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(3):		(5):	

(1) Essential safety requirement  
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(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.120  
Revision 01  
Language: E


RECOMMENDATION FOR USE

Number of pages: 1		Date: 22.08.03		Approval by :		Approved on :	
Origin : Horizontal Committee				<input checked="" type="checkbox"/> Vertical Group (Art. 11 group) 05.09.02..... <input checked="" type="checkbox"/> Horizontal Committee 06.09.02..... <input checked="" type="checkbox"/> Standing Committee 11.06.03.....			
Question related to: Directive 89/686/EEC				EN/prEN:		Other:	
Annex:		Article: 11.A.3		Clause:			
Key words: category III product							
Question: A PPE is classed as category III because the manufacturer claims one or more product features that qualify category III. Can the tests required under article 11.A be limited to performance against this / these requirements?							
Solution: No. Once a PPE is claimed to meet performance requirements that qualify category III, for whatever reason, the entire PPE item is classed as category III and not just single performance requirements. There should be no difference in approach between all category III PPE with respect to deciding which performance requirements should be tested on 11.A samples.							
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)							
(3):				(5):			

(1) Essential safety requirement  
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(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified


	<p style="text-align: center;">CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments</p> <p style="text-align: center;">RECOMMENDATION FOR USE</p>	<p>CNB/P/00.122 Revision 03 Language: E</p>
Number of pages: 1	Date: 12.07.2005	Approval by : _____ Approved on : _____
Origin : BSIF		<input type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee .....03.12.2004..... <input checked="" type="checkbox"/> Standing Committee .....30.06.2005.....
Question related to: Directive 89/686/EEC	EN/prEN: _____	Other: _____
Annex: _____	Article: 10 and 11A	Clause: _____
Key words: retention of representative samples		
Question: Is there any requirement in the PPE Directive for notified bodies to retain samples of the equipment that they have type-examined (Article 10) or tested during the annual control of the final product (Article 11)?		
Solution: No.		
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)		

(1) Essential safety requirement  
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(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified



	<p>CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments</p> <p>RECOMMENDATION FOR USE</p>	<p>CNB/P/00.124 Revision 02 Language: E</p>
<p>Number of pages: 1</p>	<p>Date: 12.07.2005</p>	<p>Approval by : _____ Approved on : _____</p>
<p>Origin : Horizontal Committee (submitted by SATRA)</p>		<p> <input type="checkbox"/> Vertical Group  <input checked="" type="checkbox"/> Horizontal Committee      03.12.2005  <input checked="" type="checkbox"/> Standing Committee         30.06.2005 </p>
<p>Question related to: Directive 89/686/EEC</p>	<p>EN/prEN: _____</p>	<p>Other: BS DD 253</p>
<p>Annex: _____ Article: _____</p>	<p>Clause: _____</p>	
<p>Key words: Boil-and-bite mouth guards</p>		
<p>Question: Is it possible for a Notified Body to issue an EC Type Examination Certificate for a part completed product, in particular, mouth formed mouth guards (often termed Boil and Bite mouth guards) which require the end user to mould the mouth guard to its final shape by following a set of simple instructions supplied with the guard ?</p>		
<p>Solution: Yes – Provided that if the user instructions are followed (in every way that they can be interpreted) it always results in a compliant product.</p>		
<p>Sent for information to:    <input type="checkbox"/> members of the VG    <input type="checkbox"/> other(s) VG    <input checked="" type="checkbox"/> HC (2)    <input type="checkbox"/> TC (3)    <input checked="" type="checkbox"/> SC (4)    <input type="checkbox"/> other (5)</p> <p style="text-align: center;">(3): _____ (5): _____</p>		

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(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.125  
Revision 05  
Language: E

PROPOSAL FOR ENQUIRY

Number of pages: 2	Date: 20.04.2011	Approval by :	Approved on :
Origin: Horizontal Committee Article 11 Ad hoc group		<input checked="" type="checkbox"/> Article 11 Ad hoc Group	16/10/2008.....
		<input checked="" type="checkbox"/> Horizontal Committee	24/06/2009.....
		<input checked="" type="checkbox"/> Standing Committee	20/04/2011.....
Question related to: Directive 89/686/EEC	EN/prEN:	Other:	
Annex: Article: 11.A	Clause:		
Key words: Uniformity of production, article 11.A.			
Question: What is the correct interpretation of the requirements of article 11.A?			
Proposed Solutions.  See attached.			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input checked="" type="checkbox"/> other (5) (5): Article 11 Ad hoc group, EU Commission			

(1) Essential safety requirement  
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(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified

**Article 11A interpretation, 1st December 2004, Article 11 ad-hoc committee. Revised 16th October 2008**

**EC quality control system for the final product.**

**1.**

A manufacturer shall take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and tests, ensures the homogeneity of production and the conformity of PPE with the type described in the EC type-examination certificate and with the specification / standard referenced on the EC type-examination certificate.

**2.**

A body of which notification has been given, chosen by a manufacturer, shall carry out the necessary checks. Those checks shall be carried out at a minimum of one per year, starting from the date of initial certificate issue.

Before the CE mark can be applied to PPE to be covered by this article, the manufacturer, as a minimum, must have entered in to an agreement with a notified body for the administration of this article.

The necessary checks shall include both 2A and 2B: -

**2 A.**

Selection of product samples by the notified body, or an independent representative of the body. Selection shall be made at a location agreed between the notified body and manufacturer.

The samples shall be randomly selected from available stock and be representative of the certified range. The samples shall be examined by the notified body to confirm that the manufactured PPE is as type-examined and remain in conformity with the standard or specification referenced on the corresponding valid type-examination certificate.

**AND**

**2B.**

The notified body shall identify any instances of production not being homogeneous by one of the following:

(i). Once per year, carry out on-site review of company production and test records. Review to take place where at least the final assembly of PPE is carried out.

(ii). Once per year, carry out an on-site audit of the production control. Audit to take place where at least the final assembly of PPE is carried out.

(iii). Once per year, take sufficient samples to evaluate production non-homogeneity.

(iv). Submission of samples throughout the year, each sample smaller in size than in (iii), based upon production information supplied by the manufacturer, to evaluate production non-homogeneity.

NOTE: Evidence of non-homogeneity to be in the terms of conformity with the PPE Directive, essentially all results to be in conformity with the applicable specification / standard. No measurement of deviation, spread of results, trends etc.

The test chosen to evaluate non-homogeneity to be a simple, straightforward, objective test, directly related to the performance of the product.

**3.**

Where a body is not the body that issued the relevant EC type-examination certificate, it shall contact the body of which notification has been given in the event of difficulties in connection with the assessment of the production control or conformity of samples.

**4.**

The body of which notification has been given shall provide the manufacturer with a report. If the report concludes that production is not homogeneous or that the PPE examined do not conform to the type described in the EC type-examination certificate or the referenced standards / specifications, the body shall take measures appropriate to the nature of the fault or faults recorded, and inform the Member State which gave notification thereof accordingly.


Where appropriate, withdrawal of EC type-examination certificates and / or authority to use the notified body number shall be considered.

**5.**

The manufacturer must be able to present, on request, the report of the body of which notification has been given.

Notes: -

Appropriate tests performed by the manufacturer may not be as specified in the standard. Where this is the case, evidence of correlation must be available.


		CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments  <b>RECOMMENDATION FOR USE</b>		CNB/P/00.126 Revision 02 Language: E	
		Number of pages: 1	Date: 26.10.06	Approval by :	Approved on :
Origin : INSPEC		<input checked="" type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee <input checked="" type="checkbox"/> Standing Committee		..... 26.08.2005..... 31.07.2006.....	
Question related to:		EN/prEN: 17025		Other:	
Annex:		Article:		Clause: 5.10.3.1 c)	
Key words: Uncertainty of measurement					
Question: When notified bodies commission testing on test laboratories complying with EN/ISO/IEC 17025, and the reference specification includes pass / fail criteria, does the notified body have to make a specific request for uncertainty of measurement to be included in the test report?					
Solution: No. EN/ISO/IEC 17025 includes a clear requirement for uncertainties of measurement to be available and reported where the uncertainty might affect compliance with pass / fail criteria. In such cases, the test laboratory has to include the uncertainty.					
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input checked="" type="checkbox"/> other (5)					
(3):			(5): Article 11 A/B Ad hoc group		

(1) Essential safety requirement  
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 (4) EEC Standing Committee 89/392

(5) To be specified




	<p>CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments</p> <p>RECOMMENDATION FOR USE</p>	<p>CNB/P/00.128 Revision 02 Language: E</p>
<p>Number of pages: 1</p>	<p>Date: 26.10.06</p>	<p>Approval by : _____ Approved on : _____</p>
<p>Origin : Exam / Advisory Panel</p>		<p><input type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee .....05.05.06..... <input checked="" type="checkbox"/> Standing Committee .....31.07.06.....</p>
<p>Question related to: Directive 89/686/EEC</p>	<p>EN/prEN: _____</p>	<p>Other: _____</p>
<p>Annex: _____ Article: 1, 2 c)</p>	<p>Clause: _____</p>	
<p>Key words: Interchangeable components of breathing apparatus</p>		
<p>Question: Who can apply for EC type examination of interchangeable components in the meaning of Article 1, 2 c) of the Directive 89/686/EEC?</p>		
<p>Solution: The manufacturer of the interchangeable component must be identical with the manufacturer of the complete PPE or protective equipment, or there must be a contractual agreement between them, which authorises the manufacturer of the interchangeable component.</p> <p>(see also RfU 00.038, rev. 03)</p>		
<p>Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)</p> <p>(3): _____ (5): _____</p>		

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(4) EEC Standing Committee 89/392


(5) To be specified

	<p>CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments</p> <p>RECOMMENDATION FOR USE</p>	<p>CNB/P/00.129 Revision 02 Language: E</p>
Number of pages: 1	Date: 26.10.06	Approval by : _____ Approved on : _____
Origin : Exam / Advisory Panel		<input type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee .....05.05.06..... <input checked="" type="checkbox"/> Standing Committee .....31.07.06.....
Question related to: Directive 89/686/EEC	EN/prEN: _____	Other: _____
Annex: _____	Article: 1, 2 c)	Clause: _____
Key words: Interchangeable components of breathing apparatus		
Question: Do interchangeable components of protective equipment that was placed on the market before the end of the transition period fall under the scope of Directive 89/686/EEC?		
Solution: Even if the original equipment is not CE marked, such interchangeable components fall under the scope of the PPE Directive. The suitability of the component for the intended use of the PPE in the protective equipment must be assessed and certified. The notified body must have access to the complete documentation concerning the whole equipment (test reports and certificates, if existing). A simple certificate confirming equivalence with the part to be replaced is not enough.		
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)		

(1) Essential safety requirement  
(2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments  RECOMMENDATION FOR USE		CNB/P/00.130 Revision 02 Language: E
	Number of pages: 2	Date: 26.10.06	Approval by :
Origin : Article 11 Ad Hoc Group		<input checked="" type="checkbox"/> Article 11 Ad hoc group <input checked="" type="checkbox"/> Horizontal Committee <input checked="" type="checkbox"/> Standing Committee	03.05.06..... 05.05.06..... 31.07.06.....
Question related to: Directive 89/686/EEC		EN/prEN:	Other:
Annex:	Article:	----- Clause:	
Key words: Own-brand certificates			
Question: How should applications for own brand certificates be dealt with?			
Solution:  See attached			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			

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(5) To be specified

## Own Brand manufacturers type-examination certificates, Article 10.

Any person / company / organisation placing a product on to the market in their own name is the manufacturer of that product within the terms of the PPE Directive. It then follows that the manufacturer must make an application in their own name and be issued with certificates that support the CE marking of the PPE.

It is common practice for original manufacturers to offer their product to one or more companies who wish to sell the product as their own. There will be no identifiable link back to the original manufacturer in the market place.

The product offered for sale by the own brand manufacturer will be identical to the original product except for marking and probably user instructions. All other elements of the technical file can be applied to the own brand product.

The own brand manufacturer will be required to raise and sign an EC declaration before placing CE marked product on the market. This will include a statement covering article 11 for category III PPE.

The own brand certificate will only remain valid while the cross-referenced original certificate remains valid.

As the own brand manufacturer is legally responsible for ensuring that the product(s) meet the requirements of the directive, it is necessary for the minimum acceptable level of control and responsibilities to be established with the PPE notified bodies.

Proposed conditions to be fulfilled before the granting of certification for an own brand product: -

1. The original manufacturer to hold a valid type-examination certificate and if category III, to provide evidence of current 11.A or 11.B supervision.
2. Written agreement to be submitted, signed by both parties (original manufacturer & own brand manufacturer), covering the following:
  - Confirmation that the PPE subject to the current application is physically identical to product xxx, which is covered by type-examination certificate yyy.
  - Any difference between the original submission and this application to be listed.
  - Confirmation from the original manufacturer that only product fully compliant with type-examination certificate xxx will be supplied to own brand manufacturer yyy as the specified model.
  - Confirmation that the original manufacturer will advise the own brand manufacturer of any changes affecting the validity of either the type-examination certificate and for category III PPE, the article 11 supervision.
  - Any proposed changes to the product will be sent to both the notified body and the own brand manufacturer before proceeding with the change.
  - Confirmation that the original technical file will be made available to the own brand manufacturer's notified body to support their application for certification and for category III PPE, article 11 documents.
  - Confirmation that both the original manufacturer and own brand manufacturer will inform each other of any incidents involving the products covered by the agreement
3. A copy of the EC type-examination certificate from the original manufacturer plus any documents that differ from the original technical file, e.g. marking and user information and access to the original technical file.  
 The notified body should review the user information and labelling of the own brand manufacturer in order to confirm it meets the requirements of the Directive.  
 A copy of the technical file amendments is then to be maintained by the own brand manufacturer and will be subject to review by the notified body during any ongoing surveillance activities.
4. For category III PPE, the article 11 notified body will decide during the review of the own brand manufacturer's submission, activities etc, whether or not the premises of the own brand manufacturer need to be visited in the article 11 supervision.
5. The type-examination certificate issued to the own brand manufacture will identify them as the manufacturer and will only reference the model identity as used by the own brand manufacture. It is proposed that the original certificate does not need to be referenced on the certificate, but the NB holds this information, should it be required.



Confidential

Report number and date:

**Article 11.A Annual Surveillance Report****Notified Body – name / address / number:****Certificate holder:****Period covered by report:****General Reference Documents:**

Recommendation for use sheet, 125, revision 02.

PPE Directive 89/686/EEC, Article 11.A

EC Type-examination certificate numbers covered by the surveillance:

Harmonised standards / technical specifications within the scope of the surveillance:

**A. Annual assessment of product compliance with standard / specification and type-examined, reference 2A of sheet 125****1. Location(s) visited and dates:****a. Selection carried out by..... Relationship to notified body.....****2b. Company representative, name and position.....****3. Relationship of company visited to type-examination certificate holder**

Certificate Holder	Production site	Importer	Secondary production site
		Distributor	Retail Outlet

European office of same company                      Other (please specify)

List of PPE            - available  
                              - not available  
                              - not selected  
                              - selected plus lot / batch numbers

**4. Attached reference documents**

Visit report, number xxxxxxx                      Test report, number yyyyyyy

**5. Sample selection was positive / negative. Product testing was positive / negative****6. Sample selection and testing demonstrated compliance with the reference specification / standard and type-examined, yes / no.****B. Annual assessment of production not being homogeneous, reference 2B of sheet 125****1. Method employed to perform assessment, please specify:**

2B(i) - On-site review of production and test records.

2B(ii) - On-site audit of production control.

2B(iii) - Production non-homogeneity assessed by selection of a single, large sample.

2B(iv) - Production non-homogeneity assessed by assessment of samples throughout the year.

**2a. Assessment(s) carried by ..... Relationship to notified body. ....****2b. Company representative, name and position.....**

**Confidential**

**Report number and date:**

**Article 11.A Annual Surveillance Report**

**3. Attached reference documents.**

**Visit report(s), number xxxxxx      Test report(s), number yyyyyyy**

**4. According to our judgement, the assessment concluded that production was not homogeneous, yes / no.**


**Justification of nonconformities**

**Conclusion of notified body:**

**Overall conclusion of the annual surveillance, positive / negative.**

**Signature..... Name and position ..... Date .....**



	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>	CNB/P/00.133 Revision 02 Language: E
Number of pages: 1	Date: 15.08.08	Approval by : _____ Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee <input checked="" type="checkbox"/> Standing Committee
Question related to: Directive 89/686/EEC	EN/prEN: _____	Other: _____
Annex: _____ Article: 10/11	Clause: _____	
Key words: Traceability of article 10 technical file documents		
Question: What are the minimum criteria to guarantee the traceability / identification of documents within the technical file approved for an EC type examination certificate?		
Solution: In order to assure the notified body that carries out Article 11 procedures that the technical file as well as the model of the information supplied by the manufacturer, which are part of the technical documentation that must be presented by the manufacturer, correspond to the documents assessed during the EC type examination, the notified body that carries out the EC type examination will send back to the certificate holder at least a copy of the marking of the PPE and of the information supplied by the manufacturer. These documents must be dated and identified.		
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)		

(1) Essential safety requirement  
 (2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
 (4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.134  
Revision 02  
Language: E

RECOMMENDATION FOR USE

Number of pages: 1	Date: 15.08.08	Approval by :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group	.....
		<input checked="" type="checkbox"/> Horizontal Committee	09.02.07.....
		<input checked="" type="checkbox"/> Standing Committee	15.07.08.....
Question related to: Directive 89/686/EEC		EN/prEN:	Other:
Annex:	Article: 10, 11	-----	
Clause:		-----	
Key words: Article 11 assessment, EC type examination certificate			
Question: Should the notified body that carries out EC type examination for a category 3 product check, as part of its responsibilities according to articles 10 (1) and 10 (5), that an Article 11 assessment is present or in process?			
Solution: Yes.			
Sent for information to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(3):		(5):	

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(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified



**CO-ORDINATION OF NOTIFIED BODIES**  
**PPE-Directive 89/686/EEC + amendments**

CNB/P/00.135  
Revision 04  
Language: E

**RECOMMENDATION FOR USE**

Number of pages: 6	Date: 20.04.2011	Approval by :	Approved on :
Origin : Horizontal Committee, Article 11 Ad hoc group		<input checked="" type="checkbox"/> Ad-hoc Committee	..18.10.2009.....
		<input checked="" type="checkbox"/> Horizontal Committee	..18.10.2009.....
		<input checked="" type="checkbox"/> Standing Committee	..20.04.2011.....

Question related to:	EN/prEN:	Other:
Annex: Article: 11B	Clause:	

Key words:  
11B minimum requirements

Question:  
What are the minimum requirements that systems complying with 11B have to cover?

Solution:  
The minimum requirements are as attached pages, 2 to 6.

NOTE: Recommendation for use sheet 00.119 is replaced by this sheet and will therefore be withdrawn.

Sent to:  members of the VG  other(s) VG  HC (2)  TC (3)  SC (4)  other (5)

(5): EU Commission

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(5) To be specified

**The system shall be documented in the form of a manual, procedures and supporting work instructions or similar. The scope of the system shall be specified.**

**The system requirements are limited to category III PPE, CE marked under the PPE Directive 89/686/EEC**

Heading, with reference to ISO9001:2008	Comments
<p><b>4 Quality management system</b></p> <p><b>4.1 General requirements</b> Comply with Clause 4.1 of ISO 9001:2008</p> <p>The quality system ensures compliance of the product with the product described in the EC-Type Examination Certificate(s).</p> <p>System shall be documented in the form of manuals, procedures and work instructions.</p>	<p>Shall include or reference quality objectives.</p> <p>Clear identification and control mechanisms for any outsourced processes to be documented, especially applicable where the company does not manufacture the PPE. Cross reference clauses 7.4.1</p>
<p><b>4.2 Documentation requirements</b> Comply with Clause 4.2 of ISO 9001:2008</p> <p><b>4.2.1 General</b> Complies with Clause 4.2.1 of ISO 9001:2008</p> <p><b>4.2.2 Quality manual</b> Complies with Clause 4.2.2 of ISO 9001 :2008</p> <p><b>4.2.3 Control of documents</b> Complies with Clause 4.2.3 of ISO 9001:2008</p>	<p>To include technical file documents, certificates and external standards, e.g. ENs. To include any external documents that are relevant to the PPE in question, e.g. standards.</p>
<p><b>4.2.4 Control of quality records</b> Complies with Clause 4.2.4 of ISO 9001:2008</p> <p>At least the following documents are retained for at least 10 years after supply of the last item:</p> <p>Those arising from regulatory requirements Training records Inspection and test data Calibration data</p>	<p>Retention period to clearly specify period after supply of the last production item.</p>
<p><b>5 Management responsibility</b></p> <p><b>5.1 Management commitment</b> Complies with Clause 5.1 of ISO 9001 :2008</p>	
<p><b>5.3 Quality policy</b> Complies with Clause 5.3 of ISO 9001:2008</p>	
<p><b>5.4 Planning</b></p> <p><b>5.4.1 Quality objectives</b> Complies with Clause 5.4.1 of ISO 9001:2008</p> <p><b>5.4.2 Quality planning</b> Complies with Clause 5.4.2 of ISO 9001:2008</p> <p>The quality system ensures compliance of the product with the EC-type examination certificate(s) All adopted elements, requirements and provisions are documented in a systematic and orderly manner in the form of written policies, procedures and instruction.</p>	

<p><b>5.5 Responsibility, authority and communication</b></p> <p><b>5.5.1 Responsibility and authority</b></p> <p>Complies with Clause 5.5.1 of ISO 9001:2008</p> <p>The following shall be defined:</p> <p>A. Need to liaise with notified body responsible for the EC type-examination in case of changes to the design defined in the EC-type examination certificate and the technical documentation</p> <p>B. Need to liaise with notified body responsible for the assessment of the quality system with respect to updating of the quality system in case of changes of quality system.</p> <p>C. Need to liaise with notified body responsible for the assessment of the quality system with respect to updating of the quality system in case of changes made to the product or technical file</p> <p><b>5.5.2 Management representative</b></p> <p>Complies with Clause 5.5.2 of ISO 9001 :2008</p> <p><b>5.5.3 Internal communication</b></p> <p>Complies with Clause 5.5.3 of ISO 9001:2008</p>	<p>Position(s) with responsibility and authority for product quality and contact / advising notified body of any quality system or product problems to be specified.</p>
<p><b>5.6 Management review</b></p> <p><b>5.6.1 General</b></p> <p>Complies with Clause 5.6.1 of ISO 9001:2008</p> <p>A. Intervals should be at least every 12 months, but with a maximum of 14 months</p> <p>B. Top management chairs the review</p> <p>C. The authorized person(s) participate(s) in the review</p> <p><b>5.6.2 Review input</b></p> <p>Complies with Clause 5.6.2 of ISO 9001:2008</p> <p><b>5.6.3 Review output</b></p> <p>Complies with Clause 5.6.3 of ISO 9001 :2008</p>	<p>The review and audit systems must include those departments / positions responsible for compliance with the PPE Directive.</p>
<p><b>6 Resource management</b></p> <p><b>6.1 Provision of resources</b></p> <p>Complies with Clause 6.1 of ISO 9001 :2008</p> <p><b>6.2 Human resources</b></p> <p><b>6.2.1 General</b></p> <p>Complies with Clause 6.2.1 of ISO 9001:2008</p> <p><b>6.2.2.Competence, awareness and training</b></p> <p>Complies with Clause 6.2.2 of ISO 9001 :2008</p> <p><b>6.3 Infrastructure</b></p> <p>Complies with Clause 6.3 of ISO 9001 :2008</p> <p><b>6.4 Work environment</b></p> <p>Complies with Clause 6.4 of ISO 9001 :2008</p>	<p>To include all personnel involved in those system elements covered by these requirements.</p>
<p><b>7 Product realization</b></p> <p><b>7.1 Planning of product realization</b></p> <p>Complies with Clause 7.1 of ISO 9001:2008</p>	

<p><b>7.4 Purchasing.</b></p> <p><b>7.4.1 Purchasing process</b></p> <p>Complies with Clause 7.4.1 of ISO 9001:2008</p> <p>Manufacture, tests and final inspection sub-contracted (the responsibility to ensure compliance to specific requirements cannot be sub-contracted)</p> <p>A. Subcontractor has been selected after an evaluation has demonstrated the capability of ensuring compliance with all specific requirements</p> <p>B. The evaluation has been performed by one of the following methods;</p> <ul style="list-style-type: none"> <li>- third party quality system certification</li> <li>- documented evaluation which provides objective evidence of the capabilities</li> <li>- documented site assessment to ensure all relevant capabilities</li> </ul> <p>C. Where the features affecting the type of protection cannot be verified at a later stage, the evaluation shall include initial and periodic site assessments at the suppliers premises to ensure that relevant controls are available, documented, understood and effective</p> <p>D. Suppliers not used for a period of one year are re-evaluated prior to placing of the contract</p> <p>E. Ability of supplier is reviewed at least once a year</p>	<p>The Notified Body is responsible for ensuring that the manufacturer's quality system complies with Article 11B requirements, and this may include on-site assessment of any sub-contracted activities which potentially impact upon conformity with the EC Type Examination and / or Article 11B.</p>
<p><b>7.4.2 Purchasing information</b></p> <p>Complies with Clause 7.4.2 of ISO 9001:2008</p> <p><b>7.4.3 Verification of purchased products</b></p> <p>Complies with Clause 7.4.3 of ISO 9001:2008</p> <p>A. Verification arrangements are implemented if purchased product can compromise the type of protection</p> <p>B. Routine tests or inspections confirmed with declaration of conformity.</p>	
<p><b>7.5 Production and service operations</b></p> <p><b>7.5.1 Control of production and service provision</b></p> <p>Complies with Clause 7.5.1 of ISO 9001:2008</p> <p>Requirements contained in the EC-Type Examination Certificates are considered.</p> <p><b>7.5.2 Validation of processes for production and service provision</b></p> <p>Complies with Clause 7.5.2 of ISO 9001:2008</p> <p><b>7.5.3 Identification and traceability</b></p> <p>Complies with Clause 7.5.3 of ISO 9001:2008</p> <p>Procedures for product identification during all stages of production, final equipment inspection, testing and placing on the market are established and maintained</p> <p><b>7.5.4 Customer property</b></p> <p>Complies with Clause 7.5.3 of ISO 9001:2008</p> <p><b>7.5.5 Preservation of product</b></p> <p>Complies with Clause 7.5.4 of ISO 9001 :2008</p>	<p>7.5.1 and 7.5.2 shall only apply where activities are carried out with respect to confirming compliance with standard / specification / type.</p> <p>Traceability is not required. Identification of product is required to cover type, model, part number etc.</p>

<p><b>7.6 Control of measuring and monitoring devices</b> Complies with Clause 7,6 of ISO 9001 :2008</p> <p>If the certificate of the calibrated instrument does not bear the accreditation logo of a national authority then the certificate shall contain the following:</p> <ul style="list-style-type: none"> <li>-an unambiguous identification of the item calibrated</li> <li>-traceability to (inter)national standards</li> <li>-the method of calibration</li> <li>-a statement of compliance with any relevant specification</li> <li>-the calibration results</li> <li>-the uncertainty of measurement, where relevant</li> <li>-the environmental conditions, where relevant</li> <li>-the date of calibration</li> <li>-the signature of the person under whose authority the certificate was issued</li> <li>-the name and address of issuing organization and the date of the certificate</li> <li>-a unique identification of the calibration certificate</li> </ul>	
<p><b>8 Measurement, analyses and improvement</b> <b>8.1 General</b> Complies with Clause 8.1 of ISO 9001:2008</p>	
<p><b>8.2 Measuring and monitoring</b></p> <p><b>8.2.2 Internal audit</b> Complies with Clause 8.2.2 of ISO 9001:2008 The audit program addresses the effectiveness of the elements of the quality system described in this standard. The audits should be carried out at least every 12 months, but within a maximum of 14 months</p> <p><b>8.2.3 Monitoring and measurement of processes</b> Complies with Clause 8.2.3 of ISO 9001:2008</p> <p><b>8.2.4 Measurement and monitoring of product</b> Complies with Clause 8.2.4 of ISO 9001 :2008</p> <p>The system shall include inspection and testing from purchased material to finished product, to the extent necessary to demonstrate continued compliance with the type-examined and the reference product specification, normally a standard. These activities shall be carried out by the manufacturer on a regular basis and shall be linked to production volumes, time or both.</p> <p>To include correct marking of the product, including the CE mark format and user information to include NB details.</p>	
<p><b>8.3 Control of nonconformity</b> Complies with Clause 8.3 of ISO 9001 :2008</p> <ol style="list-style-type: none"> <li>a) There shall be a system for the customer to be identified</li> <li>b) The manufacturer takes action if nonconforming product has been supplied to a customer</li> <li>c) In case of b) the manufacturer informs the customer and the Notified Body responsible for 11.B supervision.</li> <li>d) In case of b) and the nature of the nonconformity could affect user protection, and if not possible to trace the product, then additional actions shall be taken to inform the users, for example, notices placed in appropriate publications</li> <li>e) Product concessions that could affect user safety are not permitted. All concessions to be documented and authorised.</li> </ol>	
<p><b>8.4 Analyses of data</b> Complies with Clause 8.4 of ISO 9001:2008</p>	

**8.5 Improvement****8.5.2 / 8.5.3 Corrective action / Preventive action**

Complies with Clause 8.5.2 of ISO 9001:2008

To include customer complaints, warranty returns and returned products

Generally the manual submitted in support of an application will be a policy document, which will outline the systems operated, and reference the on-site detailed procedures.



**CO-ORDINATION OF NOTIFIED BODIES**  
**PPE-Directive 89/686/EEC + amendments**

CNB/P/00.136  
Revision 02  
Language: E


**RECOMMENDATION FOR USE**

Number of pages: 1	Date: 15.12.2009	Approval by :	Approved on :
Origin : Advisory Panel, Horizontal Committee		<input type="checkbox"/> Ad-hoc Committee	.....
		<input checked="" type="checkbox"/> Horizontal Committee	17.10.2008
		<input checked="" type="checkbox"/> Standing Committee	26.05.2009
Question related to:	EN/prEN:	Other:	
Annex: Article: 10	Clause:	-----	
Key words: EC type examination certificates; validity			
Question: How shall revisions to standards which form the basis of EC type examination certificates be dealt with?			
Solution: Type examination certificates issues or amended after approval and publication of this Recommendation for Use sheet shall have a maximum validity of 5 years. All certificate renewals shall reference the version of the standard(s) that is/are current at the time of renewal.			
Sent to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input type="checkbox"/> SC (4) <input checked="" type="checkbox"/> other (5)			
(5) EU Commission			

(1) Essential safety requirement  
(2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified

	<b>CO-ORDINATION OF NOTIFIED BODIES</b> <b>PPE-Directive 89/686/EEC + amendments</b>  <b>RECOMMENDATION FOR USE</b>		CNB/P/ 00.137 Revision: 03 Language: E
	Number of pages : 1	Date : 20.04.2011	Approval by :
Origin : Horizontal Committee Article 11 ad-hoc group		<input checked="" type="checkbox"/> Vertical Group ..... <input checked="" type="checkbox"/> Horizontal Committee ..... <input checked="" type="checkbox"/> Standing Committee .....	31.08.2009 31.08.2009 20.04.2011
Question related to :  Annex :                      Article : Article 11A.2 RfU sheet 125, 2B(iii) and 2B(iv)	EN/prEN : ----- Clause :	Other : -----	
Key words : Failure of 11A samples			
Question :  What are the necessary actions following failures when samples are taken as required by recommendation for use sheet 125, sections 2B(iii) and 2B(iv), assessment of non-homogeneity?			
Recommended solution : The following steps should be taken: 1. Manufacturer asked to investigate the failure(s) and advise the notified body of their findings. 2. The manufacturer must inform the notified body whether or not they consider the product acceptable without modification or if the product is to be modified, and how. 3. Notified body to then determine what level of additional testing is required 4. Additional samples requested from the manufacturer and tested under the authority of the notified body 5. If additional samples pass the required testing, 11A considered completed. 6. If additional samples fail, steps 1 to 4 repeated. 7. If second set of additional samples fail, 11A certification to be withdrawn /not re-issued. NOTE: If 11A body is not the article 10 body, article 10 body to be kept informed throughout the process.			
Sent to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input checked="" type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input type="checkbox"/> SC (4) <input checked="" type="checkbox"/> other (5) (5) EU Commission			

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(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.139  
Revision 02  
Language: E

RECOMMENDATION FOR USE

Number of pages: 1	Date: 20.04.2011	Approval by :	Approved on :
Origin : Product marking with standard number		<input checked="" type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee <input checked="" type="checkbox"/> Standing Committee	19.03.2010 20.04.2011
Question related to: Directive 89/686/EEC	Annex:	Article:	EN/prEN: _____ Other: _____ Clause: _____
Key words: Marking, standard number			
Question: Can a product be marked with a national standard number in addition to the marking required by the EN? Such marking can be confusing, e.g. if the publication date of the national standard differs from that of the EN.			
Solution: Yes, marking with additional standard numbers is possible. If a product is marked with more than one standard number, the meaning shall be clearly explained in the information supplied by the manufacturer.			
Sent to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5) (5)			

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(4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.140  
Revision 02  
Language: E

RECOMMENDATION FOR USE

Number of pages: 1	Date: 20.04.2011	Approval by :	Approved on :
Origin : Vertical Group 2 "Respiratory protective equipment"		<input checked="" type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee <input checked="" type="checkbox"/> Standing Committee	19.03.2010 20.04.2011
Question related to:	EN/prEN:	Other:	
Annex:	Article:	Clause:	
Key words: Product marking; reference to standards			
Question: Is it allowed to use a defined term of a standard (e.g. FFP3) for marking a product without any reference to the standard?			
Solution: No.			
Sent to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5) (5)			

(1) Essential safety requirement  
(2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified



CO-ORDINATION OF NOTIFIED BODIES  
PPE-Directive 89/686/EEC + amendments

CNB/P/00.141  
Revision 02  
Language: E

RECOMMENDATION FOR USE

Number of pages: 1	Date: 20.04.2011	Approval by :	Approved on :
Origin :		<input type="checkbox"/> Vertical Group	19.03.2010
		<input checked="" type="checkbox"/> Horizontal Committee	20.04.2011
		<input checked="" type="checkbox"/> Standing Committee	
Question related to: Directive 89/686/EEC	EN/prEN:	Other:	
Annex: 2, 1.4	Article:	-----	
Clause:			
Key words:			
Information supplied by the manufacturer, address of manufacturer			
Question: The Information for the user must contain the name and the address of the manufacturer. Can the manufacturer satisfy this requirement by publishing only his website and e-mail address?			
Solution: No.			
Sent to: <input type="checkbox"/> members of the VG <input type="checkbox"/> other(s) VG <input type="checkbox"/> HC (2) <input type="checkbox"/> TC (3) <input checked="" type="checkbox"/> SC (4) <input type="checkbox"/> other (5)			
(5)			

(1) Essential safety requirement  
(2) HC = horizontal committee

(3) N° of CEN/TC (Secretary & Chairman)  
(4) EEC Standing Committee 89/392

(5) To be specified