

Annex 1

Community legislation referred to in the Guide

I	New Approach directives (i.e. directives providing for the CE marking)	Number of Directive amendment	Reference in the OJEC amendment (<i>corrigendum</i>)
1.	Council Directive of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits	73/23/EEC 93/68/EEC	OJ L 77 of 26/03/73 OJ L 220 of 30/08/93 (OJ L 181 of 04/07/73)
2.	Council Directive of 25 June 1987 on the harmonisation of the laws of the Member States relating to simple pressure vessels	87/404/EEC 90/488/EEC 93/68/EEC	OJ L 220 of 08/08/87 OJ L 270 of 02/10/90 OJ L 220 of 30/08/93 (OJ L 31 of 02/02/90)
3.	Council Directive of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys	88/378/EEC 93/68/EEC	OJ L 187 of 16/07/88 OJ L 220 of 30/08/93 (OJ L 281 of 14/10/88) (OJ L 347 of 16/12/88) (OJ L 37 of 09/02/91)
4.	Council Directive of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products	89/106/EEC 93/68/EEC	OJ L 40 of 11/02/89 OJ L 220 of 30/08/93
5.	Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility	89/336/EEC 92/31/EEC 93/68/EEC (98/13/EC)	OJ L 139 of 23/05/89 OJ L 126 of 12/05/92 OJ L 220 of 30/08/93 (OJ L 74 of 12/03/98) (OJ L 144 of 27/05/89)
6.	Directive of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery	98/37/EC 98/79/EC	OJ L 207 of 23/07/98 OJ L 331 of 07/12/98 (OJ L 16 of 21/01/99)
7.	Council Directive of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment	89/686/EEC 93/68/EEC 93/95/EEC 96/58/EC	OJ L 399 of 30/12/89 OJ L 220 of 30/08/93 OJ L 276 of 09/11/93 OJ L 236 of 18/09/96
8.	Council Directive of 20 June 1990 on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments	90/384/EEC 93/68/EEC	OJ L 189 of 20/07/90 OJ L 220 of 30/08/93 (OJ L 258 of 22/09/90)
9.	Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices	90/385/EEC 93/42/EEC 93/68/EEC	OJ L 189 of 20/07/90 OJ L 169 of 12/07/93 OJ L 220 of 30/08/93 (OJ L 7 of 11/01/94) (OJ L 323 of 26/11/97)
10.	Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels	90/396/EEC 93/68/EEC	OJ L 196 of 26/07/90 OJ L 220 of 30/08/93
11.	Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels	92/42/EEC 93/68/EEC	OJ L 167 of 22/06/92 OJ L 220 of 30/08/93 (OJ L 195 of 14/07/92) (OJ L 268 of 29/10/93)
12.	Council Directive of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses	93/15/EEC	OJ L 121 of 15/05/93 (OJ L 79 of 07/04/95)
13.	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	93/42/EEC 98/79/EC	OJ L 169 of 12/07/93 OJ L 331 of 07/12/98 (OJ L 323 of 26/11/97) (OJ L 61 of 10/03/99)
14.	Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres	94/9/EC	OJ L 100 of 19/04/94 (OJ L 257 of 10/10/96)

I New Approach directives (i.e. directives providing for the CE marking)	Number of Directive amendment	Reference in the OJEC amendment (<i>corrigendum</i>)
15. Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft	94/25/EC	OJ L 164 of 30/06/94 (OJ L 127 of 10/06/95) (OJ L 17 of 21/01/97)
16. European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts	95/16/EC	OJ L 213 of 07/09/95
17. Directive 96/57/EC of the European Parliament and of the Council of 3 September 1996 on energy efficiency requirements for household electric refrigerators, freezers and combinations thereof	96/57/EC	OJ L 236 of 18/09/96
18. Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment	97/23/EC	OJ L 181 of 09/07/97 (OJ L 265 of 27/09/97)
19. Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity	98/13/EC	OJ L 74 of 12/03/98
20. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on <i>in vitro</i> diagnostic medical devices	98/79/EC	OJ L 331 of 07/12/98 (OJ L 22 of 29/01/99) (OJ L 74 of 19/03/99)
21. Directive 99/5/EC of the European Parliament and of the Council relating to radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity	99/5/EC	OJ L 91 of 07/04/99

II Directives based on the principles of the New Approach or the Global Approach, but which do not provide for the CE marking	Number of Directive amendment	Reference in the OJEC amendment (<i>corrigendum</i>)
1. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	94/62/EC	OJ L 365 of 31/12/1994
2. Council Directive 96/48/EC of 23 July 1996 on the inter-operability of the trans-European high-speed rail system	96/48/EC	OJ L 235 of 17/09/1996 (OJ L 262 of 16/10/1996)
3. Council Directive 96/98/EC of 20 December 1996 on marine equipment	96/98/EC	OJ L 46 of 17/02/1997 (OJ L 246 of 10/09/1997) (OJ L 241 of 29/08/1998)

III Proposals for directives based on the principles of the New Approach or the Global Approach	Number of Directive amendment	Reference in the OJEC amendment
1. Proposal for a Council Directive on articles of precious metal	COM/93/322 final COM/94/267 final	OJ C 318 of 25/11/93 OJ C 209 of 29/07/94
2. Proposal for a European Parliament and Council Directive relating to cableway installations designed to carry passengers	COM/93/646 final	OJ C 070 of 08/03/94
3. Proposal for a European Parliament and Council Directive on marking of packaging and on the establishment of a conformity assessment procedure for packaging	COM/96/191 final	OJ C 382 of 18/12/96
4. Proposal for a European Parliament and Council Directive on the approximation of the laws of the Member States relating to the noise emission by equipment used outdoors	COM/98/46 final	OJ C 125 of 22/04/1998

IV	Other Community directives, regulations and decisions referred to in the Guide	Number of document amendment	Reference in the OJEC amendment (corrigendum)
1.	Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products	85/374/EEC	OJ L 210 of 07/08/85 (OJ L 307 of 12/11/88)
2.	Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work	89/391/EEC	OJ L 183 of 29/06/89 (OJ L 275 of 05/10/90) (OJ L 347 of 28/11/89)
3.	Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)	89/655/EEC 95/63/EC	OJ L 393 of 30/12/89 OJ L 335 of 30/12/95 (OJ L 59 of 06/03/91) (OJ L 335 of 30/12/95) (OJ L 79 of 29/03/96)
4.	Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)	89/656/EEC	OJ L 393 of 30/12/89 (OJ L 59 of 06/03/1991)
5.	Council Directive 90/270/EEC of 29 May 1990 on the minimum safety and health requirements for work with display screen equipment (fifth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)	90/270/EEC	OJ L 156 of 21/06/90 (OJ L 171 of 04/07/90)
6.	Council Directive 92/59/EEC of 29 June 1992 on general product safety	92/59/EEC	OJ L 228 of 11/08/92
7.	Council Decision of 22 September 1992 on the adoption of an action plan for the exchange between Member State administrations of national officials who are engaged in the implementation of Community legislation required to achieve the internal market	92/481/EEC	OJ L 286 of 01/10/92
8.	Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code	2913/92	OJ L 302 of 19/10/92
9.	Commission Decision of 23 December 1992 on the setting-up of an Advisory Committee for coordination in the internal market field	93/72/EEC	OJ L 26 of 03/02/93
10.	Council Decision of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives	93/465/EEC	OJ L 220 of 30/08/93 (OJ L 282 of 17/11/93)
11.	Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries	339/93	OJ L 40 of 17/02/93 (OJ L 92 of 16/04/93) (OJ L 134 of 03/06/93) (OJ L 159 of 01/07/93)
12.	Commission Decision of 28 July 1993 establishing the list of products provided for in Article 8 of Council Regulation (EEC) No 339/93	93/583/EEC	OJ L 279 of 12/11/93
13.	Commission Decision of 12 July 1995 setting up a Committee of Senior Labour Inspectors	95/319/EC	OJ L 188 of 09/08/95 (OJ L 283 of 25/11/95)
14.	Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters	515/97	OJ L 82 of 22/03/97
15.	Decision No 889/98/EC of the European Parliament and of the Council of 7 April 1998 amending Council Decision 92/481/EEC on the adoption of an action plan for the exchange between Member State administrations of national officials who are engaged in the implementation of Community legislation required to achieve the internal market (Karolus programme)	889/98/EC	OJ L 126 of 28/04/98

IV	Other Community directives, regulations and decisions referred to in the Guide	Number of document amendment	Reference in the OJEC amendment (corrigendum)
16.	Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations	98/34/EC 98/48/EC	OJ L 204 of 21/07/98 OJ L 217 of 05/08/98
17.	Decision No 372/1999/EC of the European Parliament and of the Council of 8 February 1999 adopting a programme of Community action on injury prevention in the framework of action in the field of public health (1999 to 2003)	372/1999/EC	OJ L 46 of 20/02/99

Annex 2

Additional information concerning certain Articles of the Treaty establishing the European Community (the EC Treaty)

A. The previous numbers of Articles of the EC Treaty referred to in the Guide

Article of the EC Treaty	Previous number of the article
10	5
28	30
30	36
95	100a
133	113
137, 138	118a
226	169
227	170
228	171
249	189
251	189b

B. The text of certain Articles of the EC Treaty

Art. 10	Member States shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Treaty or resulting from action taken by the institutions of the Community. They shall facilitate the achievement of the Community's tasks. They shall abstain from any measure which could jeopardise the attainment of the objectives of this Treaty.
Art. 28	Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.
Art. 30	The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.
Art. 95	<ol style="list-style-type: none"> 1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. 2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons. 3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective. 4. If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them. 5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them. 6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether

	<p>or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.</p> <p>In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.</p> <p>When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.</p> <p>7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.</p> <p>8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.</p> <p>9. By way of derogation from the procedure laid down in Articles 226 and 227, the Commission and any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.</p> <p>10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure.</p>
<p>Art. 226</p>	<p>If the Commission considers that a Member State has failed to fulfil an obligation under this Treaty, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations.</p> <p>If the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice.</p>
<p>Art. 227</p>	<p>A Member State which considers that another Member State has failed to fulfil an obligation under this Treaty may bring the matter before the Court of Justice.</p> <p>Before a Member State brings an action against another Member State for an alleged infringement of an obligation under this Treaty, it shall bring the matter before the Commission.</p> <p>The Commission shall deliver a reasoned opinion after each of the States concerned has been given the opportunity to submit its own case and its observations on the other party's case both orally and in writing.</p> <p>If the Commission has not delivered an opinion within three months of the date on which the matter was brought before it, the absence of such opinion shall not prevent the matter from being brought before the Court of Justice.</p>
<p>Art. 228</p>	<p>1. If the Court of Justice finds that a Member State has failed to fulfil an obligation under this Treaty, the State shall be required to take the necessary measures to comply with the judgment of the Court of Justice.</p> <p>2. If the Commission considers that the Member State concerned has not taken such measures it shall, after giving that State the opportunity to submit its observations, issue a reasoned opinion specifying the points on which the Member State concerned has not complied with the judgment of the Court of Justice.</p> <p>If the Member State concerned fails to take the necessary measures to comply with the Court's judgment within the time-limit laid down by the Commission, the latter may bring the case before the Court of Justice. In so doing it shall specify the amount of the lump sum or penalty payment to be paid by the Member State concerned which it considers appropriate in the circumstances.</p> <p>If the Court of Justice finds that the Member State concerned has not complied with its judgment it may impose a lump sum or penalty payment on it.</p> <p>This procedure shall be without prejudice to Article 227.</p>
<p>Art. 249</p>	<p>In order to carry out their tasks and in accordance with the provisions of this Treaty, the European Parliament acting jointly with the Council, the Council and the Commission shall make regulations and issue directives, take decisions, make recommendations or deliver opinions.</p> <p>A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.</p> <p>A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.</p> <p>A decision shall be binding in its entirety upon those to whom it is addressed.</p> <p>Recommendations and opinions shall have no binding force.</p>

Art. 251

1. Where reference is made in this Treaty to this Article for the adoption of an act, the following procedure shall apply.
2. The Commission shall submit a proposal to the European Parliament and the Council. The Council, acting by a qualified majority after obtaining the opinion of the European Parliament,
 - if it approves all the amendments contained in the European Parliament's opinion, may adopt the proposed act thus amended;
 - if the European Parliament does not propose any amendments, may adopt the proposed act;
 - shall otherwise adopt a common position and communicate it to the European Parliament. The Council shall inform the European Parliament fully of the reasons which led it to adopt its common position. The Commission shall inform the European Parliament fully of its position.If, within three months of such communication, the European Parliament:
 - (a) approves the common position or has not taken a decision, the act in question shall be deemed to have been adopted in accordance with that common position;
 - (b) rejects, by an absolute majority of its component members, the common position, the proposed act shall be deemed not to have been adopted;
 - (c) proposes amendments to the common position by an absolute majority of its component members, the amended text shall be forwarded to the Council and to the Commission, which shall deliver an opinion on those amendments.
3. If, within three months of the matter being referred to it, the Council, acting by a qualified majority, approves all the amendments of the European Parliament, the act in question shall be deemed to have been adopted in the form of the common position thus amended; however, the Council shall act unanimously on the amendments on which the Commission has delivered a negative opinion. If the Council does not approve all the amendments, the President of the Council, in agreement with the President of the European Parliament, shall within six weeks convene a meeting of the Conciliation Committee.
4. The Conciliation Committee, which shall be composed of the members of the Council or their representatives and an equal number of representatives of the European Parliament, shall have the task of reaching agreement on a joint text, by a qualified majority of the members of the Council or their representatives and by a majority of the representatives of the European Parliament. The Commission shall take part in the Conciliation Committee's proceedings and shall take all the necessary initiatives with a view to reconciling the positions of the European Parliament and the Council. In fulfilling this task, the Conciliation Committee shall address the common position on the basis of the amendments proposed by the European Parliament.
5. If, within six weeks of its being convened, the Conciliation Committee approves a joint text, the European Parliament, acting by an absolute majority of the votes cast, and the Council, acting by a qualified majority, shall each have a period of six weeks from that approval in which to adopt the act in question in accordance with the joint text. If either of the two institutions fails to approve the proposed act within that period, it shall be deemed not to have been adopted.
6. Where the Conciliation Committee does not approve a joint text, the proposed act shall be deemed not to have been adopted.
7. The periods of three months and six weeks referred to in this Article shall be extended by a maximum of one month and two weeks respectively at the initiative of the European Parliament or the Council.

Annex 3

Additional guidance documents

I Documents related to New Approach directive		Number	Date	Language
1.	Guidelines on the application of Council Directive 73/23/EEC (electrical equipment designed for use within certain voltage limits)		12/97	ES, DA, DE, EL, EN, FR, IT, NL, PT, FI, SV
2.	Communication of the Commission with regard to the interpretative documents of Council Directive 89/106/EEC (construction products)	OJ C 62 of 28/2/94		ES, DA, DE, EL, EN, FR, IT, NL, PT
3.	The designation of approved bodies in the field of the construction products Directive	Guidance paper A	11/95	EN
4.	The definition of factory production control in technical specifications for construction products	Guidance paper B	5/95	EN
5.	The treatment of kits and systems under the construction products Directive	Guidance paper C	2/97	EN
6.	CE marking under the construction products Directive	Guidance paper D	12/98	EN
7.	Electromagnetic compatibility EMC; Guide to the application of Directive 89/336/EEC	ISBN 92-828-0762-2	12/97	DE, EN, FR
8.	Useful facts in relation to Directive 89/392/EEC (machinery)	ISBN 92-827-9200-5	97	EN
9.	Community legislation on machinery; comments on Directive 98/37/EC		99	ES, DE, EN, FR, IT
10.	Personal protective equipment (PPE); useful facts in relation to Directive 89/686/EEC	ISBN 92-827-9199-8	97	EN
11.	Guidelines relating to the demarcation between Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices, and Directive 65/65/EEC relating to medicinal products and related directives	Meddev. 2.1/3 – Rev. 5.1	3/98	EN
12.	Guidelines on a medical devices vigilance system	Meddev 2.12/1 – Rev. 3	3/98	EN
13.	Guidelines on the application of Council Directive 94/9/EC concerning equipment and protective systems intended for use in potentially explosive atmospheres		99	EN
14.	Recreational craft Directive (94/25/EC) and comments to the Directive combined		6/98	EN
15.	Handbook on implementation of Conformity Assessment Procedures relating to Directive 91/263/EEC (telecommunications terminal equipment)		11/95	EN

**II Draft Documents related to Language
New Approach directives**

1.	Draft guidance paper on the treatment of dangerous substances under the construction products Directive	EN
2.	Draft guidance paper on levels and classes in the construction products Directive	EN
3.	Draft guidance paper on transitional arrangements under the construction products Directive	EN
4.	Draft guidance paper related to pressure equipment	EN

III Documents related to the New Approach or the Global Approach in general

		Number of document	Reference in the OJEC
1.	Council Resolution of 7 May 1985 on a New Approach to technical harmonisation and standardisation		OJ C 136 of 04/06/85
2.	Council Resolution of 21 December 1989 on a Global Approach to Conformity Assessment		OJ C 10 of 16/01/90
3.	Commission Communication to the Council of 15 June 1989 on a Global Approach to certification and testing – quality measures for industrial products	COM(89) 209 final	OJ C 267 of 19/10/89
4.	Opinion of the Economic and Social Committee on the Communication from the Commission to the Council on the proposal for a Council Decision concerning the modules for various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation directives		OJ C 112 of 07/05/90
5.	Opinion of the Economic and Social Committee on the Communication from the Commission to the Council on a Global Approach to Certification and Testing		OJ C 112 of 07/05/90
6.	Council Resolution of 16 June 1994 on the development of administrative cooperation in the implementation and enforcement of Community legislation in the internal market		OJ C 179 of 01/07/94
7.	Council Resolution of 8 July 1996 on cooperation between administrations for the enforcement of legislation on the internal market		OJ C 224 of 01/08/1996
8.	Report from the Commission to the Council and the European Parliament of 13 May 1998 on the efficiency and accountability in European standardisation under the New Approach	COM(98) 291 final	

IV Certif documents related to the New Approach or the Global Approach

	Number	Date	Language
1.	Methods of coordinating the procedures governing the notification and management of notified bodies	Certif. 93/1 Rev.3	DE, EN, FR
2.	Framework for coordination and cooperation between notified bodies, Member States and the European Commission under the Community harmonisation directives based on the New Approach and the Global Approach	Certif. 94/6 Rev. 6	20/02/98 EN, FR
3.	Specifications concerning the assessment and supervision of systems applying to conformity assessment bodies with a view to their designation under the mutual recognition agreements between the European Union (EU) and certain non-member countries	Certif. 96/1	26/06/96 DE, EN, FR
4.	Procedure for designation of conformity assessment bodies (CAB) under mutual recognition agreements (MRAs) with non-member countries	Certif. 96/3 Rev. 4	6/10/98 EN, FR

IV Certif documents related to the New Approach or the Global Approach

		Number	Date	Language
5.	Various factors to be taken into account in order to clarify the meaning of CE marking	Certif. 96/4	5/11/96	DE, EN, FR
6.	Code of conduct for the functioning of the system of notified bodies	Certif. 97/1 Rev. 3	17/7/98	DE, EN, FR
7.	Accreditation and the Community's policy in the field of conformity assessment	Certif. 97/4 Rev. 2	15/12/97	DE, EN, FR
8.	The EN 45000 series of standards and the conformity assessment procedures of the Global Approach	Certif. 97/5 Rev. 1	24/3/98	DE, EN, FR
9.	Conformity marking and market surveillance	Certif. 98/2	30/1/98	DE, EN, FR
10.	The EN 45000 standards, accreditation and notification of notified bodies	Certif. 98/4	25/3/98	DE, EN, FR
11.	State of play on accreditation and the EN 45000 standard	Certif. 98/5	11/5/98	EN
12.	List of presidents and technical secretariats for notified body groups	Certif. 98/6	1/9/98	FR
13.	Implementation of mutual recognition agreements on conformity assessment (MRA) and protocols on European conformity assessment (PECA)	Certif. 98/7	24/7/98	DE, EN, FR
14.	Protocols of European conformity assessment (PECA)	Certif. 98/8	10/8/98	DE, EN, FR

V Other relevant documents

		Number	Date	Language
1.	Common standards for enterprises	ISBN 92-826-8110-6	94	ES, DA, DE, EL, EN, FR, IT, NL
2.	A commentary on Directive 83/189/EEC; a guide to the procedure for the provision of information in the field of technical standards and regulations	ISBN 92-828-2785-2	98	DE, EN, FR

Annex 4

Commission contact points

	New Approach directives	Contact		
		DG	Unit	Fax number (32-2) 29- ...
1.	Low voltage equipment (73/23/EEC, amendment 93/68/EEC)	Enterpr.	G3	66273
2.	Simple pressure vessels (87/404/EEC, amendments 90/488/EEC and 93/68/EEC)	Enterpr.	G4	66273
3.	Toys (88/378/EEC, amendment 93/68/EEC)	Enterpr.	E5	66273
4.	Construction products (89/106/EEC, amendment 93/68/EEC)	Enterpr.	G5	61065
5.	Electromagnetic compatibility (89/336/EEC, amendments 92/31/EEC and 93/68/EEC)	Enterpr.	G3	66273
6.	Machinery (98/37/EC, amendment 98/79/EC)	Enterpr.	G3	66273
7.	Personal protective equipment (89/686/EEC, amendments 93/68/EEC, 93/95/EEC and 96/58/EC)	Enterpr.	G3	66273
8.	Non-automatic weighing instruments (90/384/EEC, amendment 93/68/EEC)	Enterpr.	G4	66273
9.	Active implantable medical devices (90/385/EEC, amendments 93/42/EEC and 93/68/EEC)	Enterpr.	G4	66273
10.	Gas appliances (90/396/EEC, amendment 93/68/EEC)	Enterpr.	G4	66273
11.	Hot water boilers (92/42/EEC, amendment 93/68/EEC)	Energy	C2	64254
12.	Civil explosives (93/15/EEC)	Enterpr.	E3	50281
13.	Medical devices (93/42/EEC, amendment 98/79/EC)	Enterpr.	G4	66273
14.	Potentially explosive atmospheres (94/9/EC)	Enterpr.	G3	66273
15.	Recreational craft (94/25/EC)	Enterpr.	E6	67014
16.	Lifts (95/16/EC)	Enterpr.	G3	66273
17.	Refrigeration appliances (96/57/EC)	Energy	C1	66283
18.	Pressure equipment (97/23/EC)	Enterpr.	G4	66273
19.	Telecommunications terminal equipment (98/13/EC)	Enterpr.	G3	94157
20.	<i>In vitro</i> diagnostic medical devices (98/79/EC)	Enterpr.	G4	66273
21.	Radio and telecommunications terminal equipment (99/5/EC)	Enterpr.	G3	94157
II Directives based on the principles of the New Approach or the Global Approach, but which do not provide for the CE marking				
		DG	Unit	Fax number (32-2) 29- ...
1.	Packaging and packaging waste (94/62/EC)	Environ.	E3	91068
2.	High-speed rail systems (96/48/EC)	Enterpr.	E6	56851
3.	Marine equipment (96/98/EC)	Transp.	D3	69066

III	Proposals for directives based on the principles of the New Approach or the Global Approach	Contact		
		DG	Unit	Fax number (32-2) 29-
1.	Articles of precious metal (COM/93/322 final, amendment COM/94/267 final)	Enterpr.	G4	66273
2.	Cableway installations designed to carry passengers (COM/93/646 final)	Enterpr.	E6	56851
3.	Marking of packaging (COM/96/191 final)	Enterpr.	E1	91925
4.	Noise emissions (COM/98/46 final)	Environ.	D3	69554

IV	Other Community legislation referred to in the Guide	Contact		
		DG	Unit	Fax number (32-2) 29-
1.	Directive on product liability (85/374/EEC)	Internal market	D1	93088
2.	Directive on general product safety (92/59/EEC)	Health & consumer protection	A4	91858
3.	Decision concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking (93/465/EEC)	Enterpr.	G1	53877
4.	Regulation concerning checks on products imported from third countries (EEC No 339/93)	Internal market	D2	54351
5.	Commission Decision referring to Regulation (EEC) No 339/93	Internal market	D2	54351
6.	Council Directives concerning the minimum safety and health requirements at workplace (89/391/EEC, 89/655/EEC and amendment 95/63/EC, 89/656/EEC and 90/270/EEC)	Employment & social affairs	D6	34259
7.	Directive on the procedure for the provision of information in the field of technical standards and regulations (98/34/EC, amendment 98/48/EC) <ul style="list-style-type: none"> • As regards the part on standards • As regards the part on regulations 	Enterpr. Enterpr.	G2 F2	91675 60851

V	Horizontal issues related to New Approach directives	Contact		
		DG	Unit	Fax number (32-2) 29-
1.	Conformity assessment procedures, notified bodies (also updated lists of notified bodies), CE marking, market surveillance	Enterpr.	G1	53877
2.	Standardisation	Enterpr.	G2	91675

Annex 5

Useful web addresses

DG III Documents and publications:

<http://europa.eu.int/comm/dg03/public.htm>

References to harmonised standards in the context of New Approach directives:

<http://europa.eu.int/comm/dg03/directs/dg3b/newapproa/eurstd/harmstds/index.html>

(also access via <http://www.NewApproach.org>)

New Approach standardisation in the European internal market —

how to access European standards and standards activities on the web:

<http://www.NewApproach.org>

One stop Internet shop for business

<http://europa.eu.int/business/en/topics/standards/index.html>

Directive 98/13/EC

<http://forum.europa.eu.int/Public/irc/dg3/tcam/info/data/inforce.html>

Directive 99/5/EC

<http://forum.europa.eu.int/Public/irc/dg3/tcam/info/data/welcome.html>

Annex 5

Useful web addresses

DG III Documents and publications:

<http://europa.eu.int/comm/dg03/public.htm>

References to harmonised standards in the context of New Approach directives:

<http://europa.eu.int/comm/dg03/directs/dg3b/newapproa/eurstd/harmstds/index.html>

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Directive 98/13/EC

<http://forum.europa.eu.int/Public/irc/dg3/tcam/info/data/inforce.html>

Directive 99/5/EC

<http://forum.europa.eu.int/Public/irc/dg3/tcam/info/data/welcome.html>

Annex 6

Products submitted to New Approach directives

Each directive defines the products that are within its scope. This annex is not an exhaustive list of all products covered by the directive in question, and does not take into account that several directives exclude certain products from the field of application although they comply with the product definition used in the directive.

I	New Approach directive	Products that are as a general rule covered by the directive in question	
1.	Low voltage equipment	Electrical equipment	designed for use with a voltage rating of between 50 and 1000 volts for alternating current and between 75 and 1500 volts for direct current
2.	Simple pressure vessels	Welded vessels	manufactured in series, subjected to an internal gauge pressure greater than 0.5 bar, intended to contain air or nitrogen, and not intended to be fired
3.	Toys	Products or material	designed or clearly intended for use in play by children of less than 14 years of age
4.	Construction products	Products	which are produced for incorporation in a permanent manner in construction works (i.e. building and civil engineering works)
5.	Electromagnetic compatibility	Apparatus	i.e. all electrical and electronic appliances together with equipment and installations containing electrical and/or electronic components which are liable to cause electromagnetic disturbance or the performance of which is liable to be affected by such disturbance
6.	Machinery	Machinery	i.e. an assembly of linked parts or components at least one of which moves, with the appropriate actuators, control and power circuits, etc.; joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material; i.e. an assembly of machines which, in order to achieve the same end, are arranged and controlled to function as an integral whole; i.e. interchangeable equipment modifying the function of a machine, and the purpose of which is to be assembled with a machine or a series of different machines or with a tractor by the operator himself in so far as this equipment is not a spare part or a tool
		Safety components	placed on the market separately to fulfil a safety function when in use and the failure or malfunctioning of which endangers the safety or health of exposed persons, provided that the component is not an interchangeable equipment
7.	Personal protective equipment	Devices or appliances	designed to be worn or held by an individual for protection against one or more health and safety hazards
		Units of several devices or appliances	which have been integrally combined by the manufacture for the protection of an individual against one or more potentially simultaneous risks
		Protective devices or appliances	combined, separably or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity
		Interchangeable components	essential to the satisfactory functioning of the personal protective equipment, and used exclusively for such equipment

I	New Approach directive	Products that are as a general rule covered by the directive in question	
8.	Non-automatic weighing instruments	Measuring instruments	serving to determine the mass of a body by using the action of gravity on that body, or to determine other mass related magnitudes, quantities, parameters or characteristics; and which require the intervention of an operator during weighing
9.	Active implantable medical devices	Instruments, apparatus, appliances, material or other article, whether used alone or in combination (including any accessories or software necessary for its proper application)	which are intended by the manufacturer to be used for human beings for certain defined purposes (e.g. diagnosis, prevention, monitoring, treatment of disease); which rely for their functioning on an external source of power; which are intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice; and which are intended to remain after the procedure
10.	Gas appliances	Appliances	i.e. appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing and having, where applicable, a normal water temperature not exceeding 105 °C; or forced draught burners and heating bodies to be equipped with such burners
		Fittings	i.e. safety devices, controlling devices or regulating devices and sub-assemblies, other than forced draught burners and heating bodies to be equipped with such burners, if they are separately marketed for trade use and designed to be incorporated into an appliance burning gaseous fuel or assembled to constitute such an appliance
11.	Hot-water boilers	Combined boiler-body units	with a rated output of no less than 4 kW and no more than 400 kW; which are fired with liquid or gaseous fuels and which are designed to transmit to water the heat released from burning
		Appliances	i.e. the boiler-body designed to have a burner fitted, or the burner designed to be fitted to a boiler-body
12.	Civil explosives	Materials and articles	considered to be explosives in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations
13.	Medical devices	Instrument, apparatus, appliances, materials or other article, whether used alone or in combination (including the software necessary for its proper application)	which are intended by the manufacturer to be used for human beings for certain defined purposes (e.g. diagnosis, prevention, monitoring, treatment of disease); and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means
		Accessories	i.e. an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device
14.	Potentially explosive atmospheres	Equipment	i.e. machines, apparatus, fixed or mobile devices, control components (i.e. items essential to the safe functioning of equipment and protective system, without autonomous function) and instrumentation thereof; and detection or prevention systems intended for use in potentially explosive atmospheres (i.e. atmospheres that could become explosive due to local and operational conditions), and intended, separately or jointly, for the generation, transfer, storage, measurement, control and conversion of energy for the processing of material, and capable of causing an explosion through their own potential sources of ignition

I	New Approach directive	Products that are as a general rule covered by the directive in question	
15.	Recreational craft	Protective systems Safety devices, controlling devices and regulating devices Boats Partly completed boats Components	i.e. design units intended for use in potentially explosive atmospheres; intended to halt incipient explosions immediately and/or to limit the effective range of explosion flames and explosion pressures; and separately placed on the market for use as autonomous systems intended for use outside potentially explosive atmospheres, but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion from 2.5m to 24m hull length, measured according to the appropriate harmonised standards; and intended for sports and leisure purposes i.e. boats consisting of a hull and/or components referred to in Annex II of the Directive when separate and when installed
16.	Lifts	Appliances Safety components	permanently serving specific levels in buildings and constructions; having a car moving along guides that are rigid and inclined at an angle of more than 15 degrees to the horizontal; and intended for the transport of persons and/or goods, the car being in each case accessible used in lifts and referred to in Annex IV of the Directive
17.	Refrigeration appliances	Electric mains-operated refrigerators Frozen food storage cabinets Food freezers Combinations of these	
18.	Pressure equipment	Vessels* Piping* Safety accessories* Pressure accessories* Assemblies*	i.e. housings designed and built to contain fluids under pressure including their direct attachments up to the coupling point connecting it to other equipment i.e. piping components intended for the transport of fluids, when connected together for integration into a pressure system i.e. devices designed to protect pressure equipment against the allowable limits being exceeded i.e. devices with an operational function and having pressure-bearing housings i.e. several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole*
19.	Telecommunications terminal equipment	Equipment	intended to be connected to the public telecommunications network in order to transmit, process or receive data capable of being used either for transmission only, or for transmission and reception, or for reception only, of radio-communications signals by means of satellites or other space-based systems
20.	<i>In vitro</i> diagnostic medical devices	Instruments, apparatus, appliances, materials or other articles, whether used alone or in combination (including the software necessary for its proper application)	which are intended by the manufacturer to be used for human beings for certain defined purposes (e.g. diagnosis, prevention, monitoring, treatment or alleviation of disease); and which do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means; and which are reagent, a reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used <i>in vitro</i> for the examination of specimens derived from the human body for the purpose of providing information

* provided that the maximum allowable pressure is greater than 0.5 bar

I New Approach directive		Products that are as a general rule covered by the directive in question	
21.	Radio and telecommunications terminal equipment	Accessories	i.e. an article intended specifically by its manufacturer to be used together with others for <i>in vitro</i> diagnostic examination
		Telecommunications terminal equipment	i.e. a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks
		Radio equipment	i.e. a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilising the spectrum allocated to terrestrial/space radio communications

II Directive based on the principles of the New Approach or the Global Approach		Products that are as a general rule covered by the directive in question	
1.	Packaging and packaging waste	Products	made of any materials of any nature to be used for the containment, protection, handling, delivery and presentation of goods, from raw materials of processed goods, from the producer to the user or the consumer, as well as wastes from these products
2.	High-speed rail system	Subsystems	the trans-European high-speed rail-system is subdivided into eight subsystems; the structural subsystems: infrastructures, energy, control and command and signalling, rolling stock; the functional subsystems: maintenance, environment, operation, users
		Inter-operability constituents	i.e. any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the trans-European high-speed rail system depends either directly or indirectly
3.	Marine equipment	Equipment	listed in the annexes to the directives, which must either be placed on board a ship for use in order to comply with international instruments or is voluntarily placed on board for use, and for which the approval of the flag State administration is required according to international conventions, resolutions, circulars, and testing standards

Annex 7

Contents of conformity assessment procedures

Council Decision 93/465/EEC lays down the modules for conformity assessment, which are further defined in each directive. This annex is intended to give an overview of the tasks that are to be carried out under the responsibility of the manufacturer and the notified body, and the tasks that the manufacturer can delegate to the authorised representative. However, there are differences between the conformity assessment procedures adopted by the directives, which are not taken into account in this general presentation. Furthermore, the tasks to be carried out by the importer or the person responsible for placing on the market are described in Section 3.3. of the Guide.

Module	Manufacturer	Manufacturer or the authorised representative	Notified body
A	<ul style="list-style-type: none"> establishes a technical documentation as regards the design, manufacture and operation of the product takes all measures necessary to ensure that the manufacturing process assures compliance of the products with the technical documentation and with the applicable requirements (i.e. operates a quality system) 	<ul style="list-style-type: none"> ensures and declares that the products concerned satisfy the requirements affixes the CE marking to each product draws up a declaration of conformity keeps a copy of the declaration of conformity and the technical documentation at the disposal of the surveillance authorities 	
Aa1	<p>In addition to the responsibilities as in module A:</p> <ul style="list-style-type: none"> carries out, or has carried out on his behalf, one or more tests for each product manufactured chooses a notified body on whose responsibility the tests are carried out 	<p>In addition to the responsibilities as in module A:</p> <ul style="list-style-type: none"> affixes the notified body's identification number to follow the CE marking, if the notified body intervened during the production stage 	<ul style="list-style-type: none"> supervises the tests carried out by the manufacturer supervises the affixing of its identification number, where it was involved in conformity assessment during the production stage keeps a record of relevant information communicates to the other notified bodies relevant information (on request)
Aa2	<p>As in module A:</p> <ul style="list-style-type: none"> applies for product checks at random intervals 	<p>In addition to the responsibilities as in module A:</p> <ul style="list-style-type: none"> affixes the notified body's identification number to follow the CE marking 	<ul style="list-style-type: none"> carries out or has carried out product checks at random intervals, and for this purpose takes samples of final products supervises the affixing of its identification number keeps a record of relevant information communicates to the other notified bodies relevant information (on request)
B	<ul style="list-style-type: none"> establishes a technical documentation as regards the design, manufacture and operation of the product 	<ul style="list-style-type: none"> applies for the EC type-examination places at the disposal of the notified body one (or more) specimen(s), which is (are) representative of the production envisaged informs the notified body of all modifications to the approved product keeps the technical documentation, including a copy of the EC type-examination certificate, at the disposal of the surveillance authorities 	<ul style="list-style-type: none"> ascertains, by performing or having performed examinations and tests, that the specimen(s) meet(s) the applicable provisions and is manufactured in accordance with the technical documentation issues an EC type-examination certificate keeps a copy of the certificate and a record of other relevant technical information communicates to the other notified bodies the relevant information concerning the EC type-examination certificates (on request)

Module	Manufacturer	Manufacturer or the authorised representative	Notified body
C	<ul style="list-style-type: none"> takes all measures necessary to ensure that the manufacturing process assures compliance of the products with the type as described in the EC type-examination certificate and with the applicable requirements (i.e. operates a quality system, which includes establishing the necessary documentation) 	<ul style="list-style-type: none"> ensures and declares that the products concerned are in conformity with the EC type-examination certificate and satisfy the applicable requirements affixes the CE marking to each product draws up a declaration of conformity keeps relevant technical information and a copy of the declaration of conformity at the disposal of the surveillance authorities 	
Cbis1	As in modules C and Aa1	As in modules C and Aa1	As in module Aa1
Cbis2	As in modules C and Aa2	As in modules C and Aa2	As in module Aa2
D	<ul style="list-style-type: none"> operates an approved quality system for production, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the product category envisaged, documentation concerning the quality system and its updating, technical documentation of the approved type, a copy of the EC type-examination certificate, and the decisions and reports from the notified body) applies for the assessment of the quality system for the products concerned ensures and declares that the products concerned are in accordance with the EC type-examination certificate and satisfy the applicable requirements undertakes to fulfil the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient supports the action carried out by the notified body for surveillance purpose keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body 	<ul style="list-style-type: none"> affixes the CE marking to each product affixes the notified body's identification number to follow the CE marking draws up a declaration of conformity informs the notified body of any intended updating of the quality system keeps a copy of the declaration of conformity at the disposal of the surveillance authorities 	<ul style="list-style-type: none"> assesses the quality system to determine whether it satisfies the applicable requirements, and accordingly takes a decision supervises the affixing of its identification number carries out surveillance of the manufacturer by means of periodic and unexpected visits keeps a record of relevant technical information communicates to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (on request)

Module	Manufacturer	Manufacturer or the authorised representative	Notified body
Dbis	<ul style="list-style-type: none"> establishes a technical documentation as regards the design, manufacture and operation of the product operates an approved quality system for production, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the product category envisaged, documentation concerning the quality system and its updating, and the decisions and reports from the notified body) applies for the assessment of the quality system for the products concerned ensures and declares that the products concerned satisfy the requirements undertakes to fulfil the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient supports the action carried out by the notified body for surveillance purpose keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body 	As in module D	As in module D
E	As in module D, but operates an approved quality system for final product inspection and testing	As in module D	As in module D
Ebis	As in module Dbis, but operates an approved quality system for final product inspection and testing	As in module D	As in module D
F	<ul style="list-style-type: none"> takes all measures necessary to ensure that the manufacturing process assures conformity of the products with the type as described in the EC type-examination certificate and with the applicable requirements (i.e. operates a quality system, which includes establishing the necessary documentation) <p>Where the statistical verification is used:</p> <ul style="list-style-type: none"> presents the products in the form of homogeneous lots and takes all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced 	<ul style="list-style-type: none"> applies for certification of conformity checks and attests that the products are in conformity with the type as described in the EC type-examination certificate and satisfy the applicable requirements affixes the CE marking to each product affixes the notified body's identification number to follow the CE marking draws up a declaration of conformity keeps relevant technical information (e.g. the notified body's certificate of conformity) and a copy of the declaration of conformity at the disposal of the surveillance authorities 	<ul style="list-style-type: none"> carries out the appropriate examinations and tests in order to check the conformity of the product with the applicable requirements either by examination and testing of every product, or by examination and testing of products on a statistical basis supervises the affixing of its identification number draws up a certificate of conformity relating to the tests carried out if a lot is rejected, takes appropriate measures to prevent the putting on the market of that lot keeps a record of relevant technical information communicates to the other notified bodies relevant information (on request)

Module	Manufacturer	Manufacturer or the authorised representative	Notified body
Fbis	<ul style="list-style-type: none"> establishes a technical documentation as regards the design, manufacture and operation of the product takes all measures necessary to ensure that the manufacturing process assures conformity of the products with the applicable requirements (i.e. operates a quality system) <p>Where the statistical verification is used:</p> <ul style="list-style-type: none"> presents the products in the form of homogeneous lots and takes all measures necessary in order that the manufacturing process assures the homogeneity of each lot produced 	<ul style="list-style-type: none"> applies for certification of conformity checks and attests that the products satisfy the applicable requirements affixes the CE marking to each product affixes the notified body's identification number to follow the CE marking draws up a declaration of conformity keeps a copy of the declaration of conformity, the technical documentation and the notified body's certificate of conformity at the disposal of the surveillance authorities 	As in module F
G	<ul style="list-style-type: none"> establishes a technical documentation as regards the design, manufacture and operation of the product ensures and declares that the product concerned conforms to the applicable requirements 	<ul style="list-style-type: none"> applies for certification of conformity affixes the CE marking to each product affixes the notified body's identification number to follow the CE marking draws up a declaration of conformity keeps a copy of the declaration of conformity and the technical documentation at the disposal of the surveillance authorities 	<ul style="list-style-type: none"> examines the individual product, and carries out the appropriate tests to ensure its conformity with the relevant requirements supervises the affixing of its identification number keeps a record of relevant information draws up a certificate of conformity concerning the tests carried out communicates to the other notified bodies relevant information (on request)
H	<ul style="list-style-type: none"> operates an approved quality system for design, manufacture, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the design, the product category envisaged, documentation concerning the quality system and its updating, and the decisions and reports from a notified body) applies for the assessment of the quality system for the products concerned ensures and declares that the products concerned satisfy the applicable requirements undertakes to fulfil the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient supports the action carried out by the notified body for surveillance purpose keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body 	As in module D	As in module D

Module	Manufacturer	Manufacturer or the authorised representative	Notified body
Hbis	In addition to responsibilities as in module H: <ul style="list-style-type: none"> • applies for examination of the design • informs the notified body of any modification to the approved design 	As in module D	In addition to responsibilities as in module D: <ul style="list-style-type: none"> • examines the application • issues an EC design examination certificate, if the design meets the applicable provisions • keeps a record of the EC design examination certificates and the EC design approvals • communicates to the other notified bodies relevant information concerning the EC design examination certificates and the EC design approvals (on request)