Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (Text with EEA relevance)

ANNEX I

REFERENCE PROVISIONS FOR COMMUNITY HARMONISATION LEGISLATION FOR PRODUCTS

Chapter R1

Definitions

Chapter R2

Obligations of economic operators

Chapter R3

Conformity of the product

Chapter R4

Notification of conformity assessment bodies

Chapter R5

Safeguard procedures

ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

2. Manufacturing
3. Quality system
3.1. The manufacturer shall lodge an application for assessment of his...
3.2. The quality system shall ensure compliance of the products with...
3.3. The notified body shall assess the quality system to determine...
3.4. The manufacturer shall undertake to fulfil the obligations arising out...
3.5. The manufacturer shall keep the notified body that has approved...
4. Surveillance under the responsibility of the notified body
4.1. The purpose of surveillance is to make sure that the...
4.2. The manufacturer shall, for assessment purposes, allow the notified body...
4.3. The notified body shall carry out periodic audits to make...
4.4. In addition, the notified body may pay unexpected visits to...
5. Conformity marking and declaration of conformity
5.1. The manufacturer shall affix the required conformity marking set out...
5.2. The manufacturer shall draw up a written declaration of conformity...
6. The manufacturer shall, for a period ending at least 10...
7. Each notified body shall inform its notifying authorities of quality...
8. Authorised representative

Module D1 Quality assurance of final product inspection and testing
1. Quality assurance of final product inspection and testing is the...
2. Technical documentation
3. The manufacturer shall keep the technical documentation at the disposal...
4. Manufacturing
5. Quality system
5.1. The manufacturer shall lodge an application for assessment of his...
5.2. The quality system shall ensure compliance of the products with...
5.3. The notified body shall assess the quality system to determine...
5.4. The manufacturer shall undertake to fulfil the obligations arising out...
5.5. The manufacturer shall keep the notified body that has approved...
6. Surveillance under the responsibility of the notified body
6.1. The purpose of surveillance is to make sure that the...
6.2. The manufacturer shall, for assessment purposes, allow the notified body...
6.3. The notified body shall carry out periodic audits to make...
6.4. In addition, the notified body may pay unexpected visits to...
7. Conformity marking and declaration of conformity
7.1. The manufacturer shall affix the required conformity marking set out...
7.2. The manufacturer shall draw up a written declaration of conformity...
8. The manufacturer shall, for a period ending at least 10...
9. Each notified body shall inform its notifying authorities of quality...
10. Authorised representative

Module F Conformity to type based on product verification
1. Conformity to type based on product verification is the part...
2. Manufacturing
3. Verification
4. Verification of conformity by examination and testing of every product...
4.1. All products shall be individually examined and appropriate tests set...
4.2. The notified body shall issue a certificate of conformity in...
5. Statistical verification of conformity
5.1. The manufacturer shall take all measures necessary so that the...
5.2. A random sample shall be taken from each lot according...
5.3. If a lot is accepted, all products of the lot...

6. The manufacturer shall, for a period ending at least 10...
7. Each notified body shall inform its notifying authorities of quality...
8. Authorised representative

Module H. Conformity based on full quality assurance plus design examination

1. Conformity based on full quality assurance plus design examination is...
2. Manufacturing
3. Quality system
3.1. The manufacturer shall lodge an application for assessment of his...
3.2. The quality system shall ensure compliance of the products with...
3.3. The notified body shall assess the quality system to determine...
3.4. The manufacturer shall undertake to fulfil the obligations arising out...
3.5. The manufacturer shall keep the notified body that has approved...
3.6. Each notified body shall inform its notifying authorities of quality...
4. Design examination
4.1. The manufacturer shall lodge an application for examination of the...
4.2. The application shall make it possible to understand the design,...
4.3. The notified body shall examine the application, and where the...
4.4. The notified body shall keep itself apprised of any changes...
4.5. Each notified body shall inform its notifying authorities of the...
4.6. The manufacturer shall keep a copy of the EC design...
5. Surveillance under the responsibility of the notified body
5.1. The purpose of surveillance is to make sure that the...
5.2. The manufacturer shall, for assessment purposes, allow the notified body...
5.3. The notified body shall carry out periodic audits to make...
5.4. In addition, the notified body may pay unexpected visits to...
6. Conformity marking and declaration of conformity
6.1. The manufacturer shall affix the required conformity marking set out...
6.2. The manufacturer shall draw up a written declaration of conformity...
7. The manufacturer shall, for a period ending at least 10...
8. Authorised representative

TABLE: CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

ANNEX III

EC DECLARATION OF CONFORMITY

1. No … (unique identification of the product):

2. Name and address of the manufacturer or his authorised representative:...

3. This declaration of conformity is issued under the sole responsibility...

4. Object of the declaration (identification of product allowing traceability. It...

5. The object of the declaration described above is in conformity...

6. References to the relevant harmonised standards used or references to...

7. Where applicable, the notified body ... (name, number) … performed...

8. Additional information:

Signed for and on behalf of: ……
(place and date of issue):
(name, function) (signature):

(**1**) OJ C 120, 16.5.2008, p. 1.

(**2**) Opinion of the European Parliament of 21 February 2008 (not yet published in the Official Journal) and Council Decision of 23 June 2008.

(**3**) OJ C 282, 25.11.2003, p. 3.

(**4**) OJ L 204, 21.7.1998, p. 37. Directive as last amended by Council Directive 2006/96/EC (OJ L 363, 20.12.2006, p. 81).

(**5**) OJ L 220, 30.8.1993, p. 23.

(**6**) OJ L 210, 7.8.1985, p. 29. Directive as amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20).

(**7**) See page 30 of this Official Journal.