Matching between modules for conformity assessment procedures of the Decision 768/2008/EC and European Standards EN ISO/IEC 17020, EN ISO/IEC 17021, EN ISO/IEC 17065

Objective

The objective of this document is to demonstrate correlation of provisions given by the appropriate Modules for conformity assessment procedures (see Decision 768/2008/EC, Annex II) with International and European standards relevant for conformity assessment bodies (CAB).

General explanatory notes

In the present comparison only those modules have been considered where independent notified bodies are involved. Those provisions of the modules not covered by requirements of the standards are indicated in the present Table. Other requirements for CAB cannot be covered by relevant International Standards, including the following: participating in the activities of the notified bodies coordination group, information of the notifying authority, keeping at the disposal of the notifying authorities, specific requirements of a notified body.

Article in the Decision 768/2008/EU, Modules	**Clauses in EN ISO/IEC 17065:2012**	**Clauses in EN ISO/IEC 17021:2011**	**Clauses in EN ISO/IEC 17020:2012**
Module B EC-type examination			
3. Application for EC-type examination	**4.1.2.1; 4.1.2.2; 7.2; 7.4.3**	Not applicable	**7.1**
4.1 Examination of the technical documentation and supporting evidence to assess the adequacy of the technical design of the product **4.2-4.4** Conformity with the technical documentation; The solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly; Corresponding with the essential requirements of the legislative	**7.2; 7.3; 7.4** (in connection with the certification scheme)	Not applicable	**7.1; 7.2**
4.5 Agreement with the manufacturer on a location where the examinations and tests will be carried out.	**4.1.2; 4.1.2.2 c); 6.2**	Not applicable	**7.1**
5. The notified body shall draw up an evaluation report. It shall release the content of that report, in full or in part, only with the agreement of the manufacturer	**4.5.1; 4.5.2; 7.12**	Not applicable	**4.2.1; 4.2.2; 7.4**
6. Issue of EC-type examination certificate - all relevant information - refuse to issue an EC-type examination certificate	**7.4.6 – 7.4.9; 7.6.6; 7.7 – 7.8**	Not applicable	**7.4;**
7. First paragraph - Follow up of generally acknowledged state of the art - determine whether such changes require further investigation and inform the manufacturer accordingly;	**7.10**	Not applicable	**5.2.2; 6.1.6 c); 7.1.4**
7. Second paragraph **-** Duty for the manufacturer to inform the notified body in case of change of modifications to the approved type	**4.1.2.2 k)**	Not applicable	**7.1.4; 8.3;**

8. - NB shall inform its notifying authorities concerning the EC-type examination certificates - NB shall inform the other notified bodies - NB shall inform the EU COM, Member States and the other notified bodies	**4.5.2**	Not applicable	
Module C1 **Conformity to type based on internal production control plus supervised product testing**			
3. Product checks For each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument. At the choice of the manufacturer, the tests shall be carried out either by an accredited in-house body or under the responsibility of a notified body, chosen by the manufacturer. Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.	**4.1.2; 4.1.3; 7.2; 7.4**	Not applicable	**7.1; 7.2; 7.3; 7.4**
Module C2 **Conformity to type based on internal production control plus supervised product checks at random intervals**			
At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks on the product, taking into account, inter alia, the technological complexity of the products and the quantity of production. An adequate sample of the final products, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or technical specifications, or equivalent tests, shall be carried out to check the conformity of the product with the relevant requirements of the legislative instrument. Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.	**4.1.2.1; 4.1.2.2**	Not applicable	**6.1; 6.2; 6.3; 7.2; 7.3; 7.4**
Module D **Conformity to type based on quality assurance of the production process**			
3. Quality system **3.1.** The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned. The application shall include: — the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well, — a written declaration that the same application has not been lodged with any other notified body, — all relevant information for the product category envisaged, — the documentation concerning the quality system, — the technical documentation of the approved type and a copy of the EC-type	**7.2; 7.3;**	**1; 9.2.1; 9.9.2** **9.2.1**	Not applicable t

examination certificate. **3.2.** The quality system shall ensure that the products are in conformity with the type described in the EC-type examination certificate and comply with the requirements of the legislative instrument that apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: — the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality, — the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, — the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and — the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	**7.4;7.9** (in connection with the certification scheme)	**7.1.1; 9,1.1** **Annex A**	
3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications. In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.		**1; 7.1.1; 7.1.3; 7.2; 9.2.3;** **7.1.3; 7.2; 9.1**	
3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.	**4.1.2 Certification agreement**	**8.1.3; 8.2.1; 8.2.3; 8.6.1;**	
3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	**4.1.2.2 k)**	**5.1.2; 9.4.2;** **8.6.3;**	

4. Surveillance under the responsibility of the notified body **4.1.** The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. **4.2.** The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular: — the quality system documentation, — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc. **4.3.** The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. **4.4.** In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.	**7.9**	**9.3;** **8.6.1** **9.3.1.1; 9.3.1.2; 9.3.2; 9.3.2.1;** **9.1.1.1; 9.1.2.1; 9.1.10; 9.5.2**	Not applicable
7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.	**7.8**	**8.1.1; 8.1.3; 8.1.4; 8.5.2 8.5.7; 9.9.1**	Not applicable
Module D1 **Quality assurance of the production process**			
5. Quality system 5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned. The application shall include: — the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well, — a written declaration that the same application has not been lodged with any other notified body, — all relevant information for the product category envisaged, — the documentation concerning the quality system, — the technical documentation referred to in point 2. **5.2.** The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent	**7.2** **7.3**	**1;** **9.2.1; 9.9.2**	Not applicable

interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: — the quality objectives and the organisational structure responsibilities and powers of the management with regard to product quality, — the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, — the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, — the quality records, such as inspection reports and test data, — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., — the means of monitoring the achievement of the required product quality and the effective operation of the quality system.			
5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification. In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.	**7.4** **7.9** (in connection with the certification scheme)	**1; 7.1.1; 7.1.3; 7.2.1; 9.1.1; 8.1.3; 9.1.10** **Annex A** **9.2.3 Audit** **9.4.2 Recertification audit**	
5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient. **5.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether reassessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	**7.10.2; 7.10;3**	**8.6.3**	
6. Surveillance under the responsibility of the notified body **6.1.** The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. **6.2.** The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular: — the quality system documentation, — the technical documentation referred to in point 2, — the quality records, such as inspection reports and test data, calibration data,	**7.9**	**9.3 Surveillance activities** **8.6.1 Information on the certification activity and requirements**	Not applicable

qualification reports on the personnel concerned, etc. **6.3.** The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. **6.4.** In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.		**9.3.1.1; 9.3.1.2; 9.3.2; 9.3.2.1;** **9.1.1.1;9.1.2.1;9.1.10;9.5 9.5.2 Short-notice audits**	
9. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.	**7.8**	**8.1.1; 8.1.3; 8.1.4; 8.5.2 8.5.7; 9.9.1**	Not applicable
Module E **Conformity to type based on product quality assurance**			
3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. (**3.2.** The quality system shall ensure compliance of the products with the type described in the EC-type examination certificate and with the applicable requirements of the legislative instrument. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: — the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality, — the examinations and tests that will be carried out after manufacture, — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., — the means of monitoring the effective operation of the quality system.) It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification. In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, in order to verify the manufacturer's ability to identify the relevant	**7.2** **7.3** **7.4; 7.9**	**9.2.1 Application 9.2.1;9.9.2** **9.1.1; 7.1.1; Annex A** **9.2.3 Audit** **9.4.2 Recertification audit 1: 7.1.1.;7.2.1; 9.1**	Not applicable

requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision. **3.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. **4.** Surveillance under the responsibility of the notified body **4.2.** The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular: — the quality system documentation, — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc. **4.3.** The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. **4.4.** In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report. **7.** Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.	**7.9** **7.8**	**8.6.3 Notice of changes by a client** **8.1.3;** **9.3 Surveillance activities** **9.3.1.1; 9.3.1.2; 9.3.2; 9.3.2.1;** **9.1.10.1** **9.5.2 Short-notice audits** **8.1.1;** **8.1.3; 8.1.4; 8.5.2 : 8.5.7; 9.9.1**	Not applicable
Module E1 **Quality assurance of final product inspection and testing**			
5. Quality system **5.1.** The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned. The application shall include: — the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well, — a written declaration that the same application has not been lodged with any other notified body,	**7.2**	**9.2.1 Application** **9.2.1;9.9.2**	Not applicable

— all relevant information for the product category envisaged, — the documentation concerning the quality system, and — the technical documentation referred to in point 2. **5.2**. The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: — the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality, — the examinations and tests that will be carried out after manufacture, — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., — the means of monitoring the effective operation of the quality system. **5.3. The notified body** shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification. In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision. **5.4.** The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient. **5.5.** The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a reassessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	**7.3** **7.4** **7.9** (in connection with the certification scheme)	**9.1.1;** **7.1.1;** **Annex A** **9.2.3 Audit** **9.4.2 Recertification audit 1: 7.1.1.;7.2.1; 9.1** **8.6.3 Notice of changes by a client** **8.1.3;**	
6. Surveillance under the responsibility of the notified body **6.1.** The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. **6.2.** The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all	**7.9**	**9.3 Surveillance activities** **9.3.1.1; 9.3.1.2; 9.3.2;**	Not applicable

necessary information, in particular: — the quality system documentation, — the technical documentation referred to in point 2, — the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc. **6.3. The notified body** shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. **6.4. In addition**, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.		**9.3.2.1;** **9.1.10.1** **9.5.2 Short-notice audits**	
9. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.	**7.8**	**8.1.1;** **8.1.3;8.1.4;8.5.2 :8.5.7;** **9.9.1**	Not applicable
Module F1 **Conformity based on product verification**			
4. Verification A notified body chosen by the manufacturer shall carry out appropriate examinations and tests to check the conformity of the products with the applicable requirements of the legislative instrument. The examinations and tests to check the conformity with those requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every product as specified in point 5, or by examination and testing of the products on a statistical basis as specified in point 6.	**4.1.2;**	Not applicable	**Introduction,** last paragraph; **7.1.1** **7.1.2**
5. Verification of conformity by examination and testing of every product **5.1**. All products shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out. **5.2.** The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility. The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.	 **7.7; 7.8** **7.4.3; 7.4.6; 7.7.1**	Not applicable	 **Introduction,** last paragraph **7.1.1** **7.1.2** **7.4**

Module G **Conformity based on unit verification**			
4. Verification A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, to check the conformity of the product with the applicable requirements of the legislative instrument, or have them carried out. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved product, or have it affixed under its responsibility. The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.	**4.1.2**	Not applicable	**7.1.1**
Module H **Conformity based on full quality assurance**			
3. Quality system **3.1.** The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned. The application shall include: – the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well, – the technical documentation for one model of each category of products intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements: – a general description of the product, – conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., – descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product, – a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied, – results of design calculations made, examinations carried out, etc., – test reports, – the documentation concerning the quality system, and – a written declaration that the same application has not been lodged with any other notified body.	**7.2** **7.3**	**9.2.1 Application** **9.2.2**	**7.1.1** **7.1.6** (application review)

3.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: – the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality, – the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements of the legislative instrument that apply to the products will be met, – the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered, – the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, – the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, – the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., – the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	**7.1** This is a requirement of the scheme	**9.1.1**	**7.1.1** This is a requirement of the scheme
3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification. In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements. The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.	**4.1.2.2** **5.1.3** **7.1** **7.4; 7.6; 7.7**	**9.2.3.1** : Stage 1 audit **9.2.3.2** : Stage 2 audit **9.1.10**	**7.1.1** **7.4**
3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.	**4.1.2.2 a)**	**5.1.2.** : Certification agreement	Not applicable

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	**4.1.2.2 k)** **7.10.2** **7.10.3**	**8.6.3.**	**7.4**
4. Surveillance under the responsibility of the notified body 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. **4.2.** The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular: – the quality system documentation, – the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc., – the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc. **4.3.** The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report **4.4.** In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.	**7.9** **4.1.2.2 c)** **7.3** **7.9.1**	**9.3 Surveillance activities** **8.6.1** **9.3.1.1; 9.3.1.2; 9.3.2; 9.3.2.1;** **9.5.2 Short-notice audits**	Not applicable
Module H1 **Conformity based on full quality assurance plus design examination**			
3. Quality system **3.1.** The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned. The application shall include: – *the name and address of the manufacturer and, if the application is lodged by the authorised rep*resentative, his name and address as well, – all relevant information for the product category envisaged, – the documentation concerning the quality system, – a written declaration that the same application has not been lodged with any other notified body. **3.2.** The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies,	**7.2** **7.3**	**9.2.1 Application**	Not applicable

procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: – the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality, – the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements of the legislative instrument that apply to the products will be met, – the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered, – the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, – the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, – the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., – the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.			
3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications. In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned	**4.1.2.2** **5.1.3** **7.1** **7.4**	**9.2.3.1:** Stage 1 audit **7.1.3;7.2.1 – 7.2.12;9.1.3** **9.2.3.2 :** Stage 2 audit **8.1.1;8.3;8.6;9.1.10**	Not applicable
3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient. Assessment decision	**4.1.2.2 a)**	**5.1.2** Certification agreement	Not applicable
3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision	**4.1.2.2 k)** **7.10.2** **7.10.3**	**8.6.3; 9.5.1.**	**7.4**

3.6. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.	**7.4**	**8.1.3, 8.1.4, 8.5.2, 8.5.**7	Not applicable
4. Design examination			
4.2. The application shall make it possible to understand the design, manufacture and operation of the product, and to assess the conformity with the requirements of the legislative instrument that apply to it. It shall include: — the name and address of the manufacturer, — a written declaration that the same application has not been lodged with any other notified body, — the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements: — a general description of the product, — conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., — descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product, — a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied, — results of design calculations made, examinations carried out, etc., and — test reports, — the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.	**4.1.2; 4.6 c);** **7.2** **7.3**	**9.2.1 Application**	**7.1.1; 7.1.2**
4.3. The notified body shall examine the application, and where the design meets the requirements of the legislative instrument that apply to the product it shall issue an EC design examination certificate to the manufacturer. The certificate shall give the name	**7.3; 7.4; 7.5; 7.6;7.7**	**Not applicable**	**7.4; Annex B**

and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. The certificate may have one or more annexes attached. The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined design to be evaluated, and to allow for in-service control, where applicable. Where the design does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.			
4.4. The notified body shall keep itself appraised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly. The manufacturer shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of the legislative instrument or the conditions for validity of the certificate. Such modifications shall require additional approval —from the notified body that issued the EC design examination certificate — in the form of an addition to the original EC design examination certificate.	**7.10.2; 7.10.3; 7.11.1** **7.12.1; 7.12.3**	**7.1.2 "Determination of competence criteria" ;** **Annex A**	**7.1.4** **6.1.2; 6.1.3**
5. Surveillance under the responsibility of the notified body **5.1.** The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. **5.2.** The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular: — the quality system documentation, — the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc., — the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc. **5.3.** The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. **5.4**. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.	**7.9** **4.1.2.2 c)** **7.3** **7.9.1**	**9.3 Surveillance activities** **8.6.1** **9.3.1.1; 9.3.1.2; 9.3.2; 9.3.2.1;** **9.5.2 Short-notice audits**	Not applicable
6. Conformity marking and declaration of conformity **6.1.** The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.	**4.1.3**	**8.4 Reference to certification and use of marks**	Not applicable