WCL CORPORATION

APPLICATION NOTE 1
ATEX DIRECTIVE IMPLEMENTATION FOR ELECTRICAL PRODUCTS INTENDED FOR INSTALLATION IN EXPLOSIVE ATMOSPHERES

ABSTRACT

A new Directive mandating CE Marking for products installed or used in explosive atmospheres is in a transition stage in the European Union (EU). Its title is “Equipment and Protective Systems for Use in Potentially Explosive Atmospheres” (94/9/EC) (ATEX Directive). This New Approach Directive replaces Old Approach Directive “Flammable Atmospheres Directive” (76/117/EEC).

Products intended to be used in explosive atmospheres must be in conformance with the new Directive and associated standards by June 30, 2003. Products not marked in accordance with these standards and this Directive will be required to be withdrawn from the market after this date. To ensure conformance to the new Directive, Second Edition Harmonized standards are required. We expect new Harmonized standards and/or Amendments will continue to be published in the Official Journal of the European Communities (OJ) over the next few years.

The scope of this paper is limited to electrical products, however the Directive also includes Protective Equipment and Internal Combustion Engines intended for use in Hazardous Locations.

This paper is intended to

1. make the reader aware of the mandatory nature of the new Directive and the deadline for implementation;
2. identify features and requirements of the new Directive that differ from the old Directive;
3. identify the Modules of Conformity Assessment for the new Directive within the scope of this paper (electrical products only);
4. identify Quality Assurance and/or Surveillance requirements of the new Directive;
5. provide a decision framework to permit the reader to prepare for timely implementation of the requirements of the new Directive, and to permit steps to be taken to prevent the necessity to withdraw products from the EU Market;
6. provide sources for additional information.

MANDATORY NATURE OF THE DIRECTIVE AND DEADLINE FOR IMPLEMENTATION

Directives are legislation enacted by the European Parliament. The European Commission, which is an organization with a staff of approximately 20,000 employees, is charged with implementing and enforcing the legislation. As a New Approach Directive, the ATEX Directive mandates CE Marking for all products included within the scope of the Directive. All provisions of the Directive become mandatory after June 30, 2003.

NEW FEATURES AND REQUIREMENTS

In addition to classification, type of protection, temperature and zone markings, equipment evaluated for conformance to the Directive will also need “Conformity Category” markings. There are Conformity Category markings for both underground and above-ground applications. These markings do not match up with zone markings. For instance, an Intrinsically Safe product acceptable in Zone 0 will require an additional marking stating that the product is suitable for Conformity Category 1 (above ground) or Conformity Category M1 (underground/mining). Products suitable for Zone 1 will additionally be marked for Category 2 or M2, and products suitable for Zone 2, will additionally be marked for Category 3.

MODULES OF CONFORMITY ASSESSMENT LEADING TO CE MARKING

See attached chart for a graphical representation of the Modules of Conformity Assessment pathways. These modules are mandated by the ATEX Directive and must be followed in order to CE Mark products that fall within the scope of the Directive. (Source: *Guide to Implementation of Directives Based on the New Approach and Global Approach*, European Commission, 2000, P. 103, ISBN 92-828-7500-8, Reprinted by permission.) NOTE: The fourth box down in the right-hand column (Annex VII) has an error. It says “Production” Quality Assurance, it should say “Product” Quality Assurance. Use the Table below to relate Articles and Annexes from the table to the more easily understood Zones and Conformity Categories.

Great care needs to be exercised in the selection of the Module of Conformity, because an incorrect selection can be quite costly and time-consuming. In general, the Modules are based upon the Conformity Categories, which, in turn, are based upon the level of ignition or explosion risk present in the area into which the product is intended to be placed. The table below will identify the Categories, equivalent IEC Classification and Zone, Permitted modules, the Relevant Article and Annex from the Directive, and

the required level of safety. This table refers only to electrical products for below-ground mining with the risk of Firedamp (Methane gas) and all above ground hazardous locations.

ATEX Conformity Category	IEC Classification /Zone All Types of Protection	Permitted Modules*	Relevant Article, Annex of Directive	Required level of safety
1 (Above ground)	IIA, IIB, IIC Zone 0	D, F, G	Art 8.1 (a) Art 8.2 Annex V	Very High
M1 (Mining)	I Zone 0	D, F, G	Art 8.1 (a) Art 8.2	Very High
2 (Above ground)	IIA, IIB, IIC Zone 1	Cbis1, E, G	Art 8.1 (b)	High
M2 (Mining)	I Zone 1	Cbis1, E, G	Art 8.1 (b)	High
3 (Above ground)	IIA, IIB, IIC Zone 2	A, G	Art 8.1 (c)	Normal

*Annex 7 of the *Guide* (page 84 to 88) attached explains the Modules of Conformity is some detail. (Attached)

Selection of the optimal module will be based upon the needs of the individual company. For some types of products intended for installation in high explosion risk areas, where the required level of safety is very high, the options are limited and the production monitoring surveillance requirement is also high.

QUALITY ASSURANCE AND/OR PRODUCTION MONITORING REQUIREMENTS

Modules of Conformity Assessment are now mandated by the ATEX Directive. These Modules are road maps showing minimum and alternate paths necessary to determine conformance with the specific requirements of the Directive. A page from a guideline document published by the European Commission is shown below. This entire guideline document, which shows all Modules of Conformity for all Directives, can be downloaded from the Internet. An address will be provided below. Examination of the Modules of Conformity shows that for some product categories, the Directive mandates production monitoring. This is different from previous EU HazLoc practice.

Choosing the appropriate Module of Conformity Assessment is critical, because implementing this module is potentially very expensive, difficult, and must be considered a long-lead item for many companies. It is a critical planning element for conformance to the Directive. Electrical equipment intended for Zones 0 and 1 (Conformance Categories 1 and 2) will require a system of production monitoring to be installed by the manufacturer. In some cases , this will mean some form of a Quality Assurance program and verification that products conform with the type.

DECISION FRAMEWORK FOR MANUFACTURERS TO PREPARE TIMELY IMPLEMENTATION OF EXISTING AND NEW PRODUCTS

Manufacturers who currently sell EU Approved HazLoc products that are not CE Marked to the ATEX Directive (some products may have CE Markings to the EMC Directive currently, but an upgrade to ATEX will be mandatory) need to contact their Notified Body (N.B.) or its domestic approvals partner and have the product file examined to determine what steps are necessary to upgrade the existing product to the requirements of the standards that are Harmonized to the new Directive.

All products, at minimum, will need revision of labeling to incorporate markings made mandatory by the Directive. In all cases, products evaluated to 1977 Standards will need technical evaluation to verify conformance to changed elements of the standard. Only the Notified Body or its domestic approvals partner can provide this evaluation. If the file review indicates that additional tests and evaluations are necessary, the lab must provide an estimate of the cost, required samples, and time necessary to complete the reevaluation.

If a product has been approved (Certified, with Type Examination Certificate issued by a Notified Body) in the past few years, part of the job may already be done, that is, the product may already have a Type Examination Certificate to the newer standard. This can easily be verified by examining the Certificate number on the Laboratory Certificate. The first two digits of this number usually indicate the year the Certificate was issued. The letter “E” appears immediately after the year on the Certificate of a product that has been evaluated to the requirements of the new standards. Letters A through D are indications that the product will need technical evaluation prior to being considered suitable for CE Marking. Two fictional certificate numbers are shown below to illustrate the difference.

BAS Ex 94C12345U
Sira Ex 98E12345U

Even with the “E” in the Certificate number the product is not necessarily fully ready for the CE Mark. In some cases, it is close--but no cigar. First, some products classed as “Components” do not require CE Marking; however, if their Certificate has the “E”, their manufacturer still needs to meet all elements of the Module of Conformity and meet the ATEX marking requirements before these products are eligible to be sold under the ATEX Directive. Second, products that do require CE Marking (“Assemblies”) need to complete all elements of the applicable Module of Conformity Assessment and markings before the CE Mark can be applied. Finally, because marking and labeling are changing, and this information is, without fail, controlled by the Notified Body, new Certificates will need to be issued for all approved products.

An example is a Zone 0 product–-now either Category 1 or M1. These products are described in Article 8.1 (a), and the CE Marking Process is shown at the top of the flowchart. First, Module B, EC Type Examination by a Notified Body, is required. Next, the manufacturer must choose between Module D, Production Quality Assurance, or Module F, Product Verification. Production Quality Assurance is primarily an ISO 9000 Quality Management System, Registered by a Notified Body (i.e., European Registrar) with certain extensions to cover quality aspects related to manufacturing products intended to be installed in Hazardous Locations. Product Verification requires a documented Quality Assurance System and individual or lot verification procedures by both the manufacturer and a Notified Body. Product Verification does not appear to be a process that is appropriate for high volume, low to mid-price products.

Zone 1 products–-now Category 2 or M2 products, have, in addition to a Production Quality Assurance Module E (Annex VII), requirement, a very onerous Module Cbis1 (Annex VI) Conformity to Type requirement. This Module requires the manufacturer to have a documented Quality Assurance system (not necessarily an ISO 9000 system), and to verify that “For each piece of equipment manufactured, tests relating to the anti-explosive protection aspects of the product shall be carried out under the responsibility of a notified body, chosen by the manufacturer.” (Source: Annex VI) The product is to be constructed in accordance to the Type Examination Certificate, a Technical File needs to be kept, each piece must be tested to the satisfaction of the N. B.,

a Declaration must be prepared, and then the product is eligible for the CE Mark. It is not completely clear what will meet the Notified Body's needs on this module, and it may in fact be variable based on product type, Category, and Notified Body.

A product that is nearing the end of its design cycle and near obsolescence may warrant a decision not to proceed at this point, and production for the EU market may be discontinued after June 30, 2001. This does not preclude the continued sale of these products in markets where they still conform to the requirements of existing Certifications. For instance, an Australia/New Zealand Certificate will still be good in these countries.

A decision not to upgrade a product may provide an opportunity to implement a new design and obtain Certification to the ATEX Directive from the beginning of the product's life. The necessity to get the product into the Certification Lab's queue before the rush is on may accelerate the development schedule, but failure to move quickly enough may keep products off the EU market well past the June 30, 2003 date.

Assuming the product has life in the market place and the cost to convert the Certificate is not prohibitive, it will be prudent to proceed as soon as possible to begin the upgrade process. Because there are thousands of products in the current market that will require upgraded certificates, and laboratory capacity in 2002 and 2003 will be stretched to the limit, the author expects extended delays for those who wait too long.

Depending upon the product, some companies may also have to use the Product Quality Assurance or Internal Control of Production Modules of Conformity Assessment. These companies should begin the process of implementing the system and engaging the Auditors early rather than late in the Transition to avoid the problem of overly long waiting periods for the Auditors' attention. Time allowances also need to be included in the event that corrective actions are required by the Auditors.

SOURCES OF ADDITIONAL INFORMATION

All companies manufacturing products covered under the ATEX Directive should have a copy of the Directive (94/9/EC), which can be obtained from a number of sources. It may be purchased from various Standards houses, (Global Documents, European Document Research, Document Center, and others). With a little legwork, a copy can be obtained in other places. Most international law libraries have the OJ on hand. Directives are published in the L series, and the research librarian can locate

and copy the document fairly cheaply. The Directive is available (without graphics) from the European Commission's website (**http://europa.eu.int/eur-lex/en/oj/index.html**). It is legal to download a single copy for your own use at their site. A Copyright Notice covering this point is available on the site.

Up-to-date copies of relevant standards for products are also necessary for the design team. There are enough differences between 1977 standards and the newer versions that the purchase is warranted. If you have prEN status standards on hand, it is still necessary to obtain the correct EN document, because significant differences may exist between the prEN status document and the EN document. It is necessary to purchase these documents from the Standards houses mentioned above or from their competitors. (We are not endorsing any of these organizations.)

A good web source for all the information in one place is the author's website **http://www.wclcorp.com**. Follow: Product Safety Links|European Links or |Standards Sellers or |Hazardous Locations links for more information. The publication mentioned previously in this article, ***Guide to Implementation of Directives Based on the New Approach and Global Approach***, can be found by following the European Links|Free download site for CE Marking Guideline. Another comprehensive web site useful to the Conformity Assessment community is SafetyLink at **http://www.safetylink.com**.

An additional source of accurate information is any North American Approvals laboratory that has an active HazLoc approvals group. Most labs have Memorandums of Understanding (MOUs) or Reciprocal Agreements with Notified Bodies that permit them direct access to their various HazLoc groups to answer questions you may have. It is advisable to craft your questions carefully to prevent the need to keep coming back for additional information.

Alternately, you may call or email the author of this article. If enough traffic is generated to develop a list of Frequently Asked Questions, we will publish such a list and answers on the website.

CONCLUSION

Less than two years remain before the ATEX Directive becomes mandatory for all products sold into European Hazardous (Classified) Locations. Manufacturers holding or contemplating obtaining European Hazardous Location approvals need to determine the steps necessary to bring their products into full compliance

with the new editions of the technical standards and to upgrade their Certificates, Markings, and, if necessary, Quality Systems to prevent the need to withdraw products from the European Union Market. Now is also a good time to review conformance to EMC requirements for these same products, because several generic standards have been withdrawn and replaced with product-specific EMC standards. In general, the newer EMC standards mandate more immunity tests or modifications of test levels.

WCL Corporation is in the business of providing consulting services associated with meeting the needs of clients regarding the ATEX Directive and other HazLoc approvals. Parties interested in determining their status re: the ATEX Directive can contact the author at the email address below.

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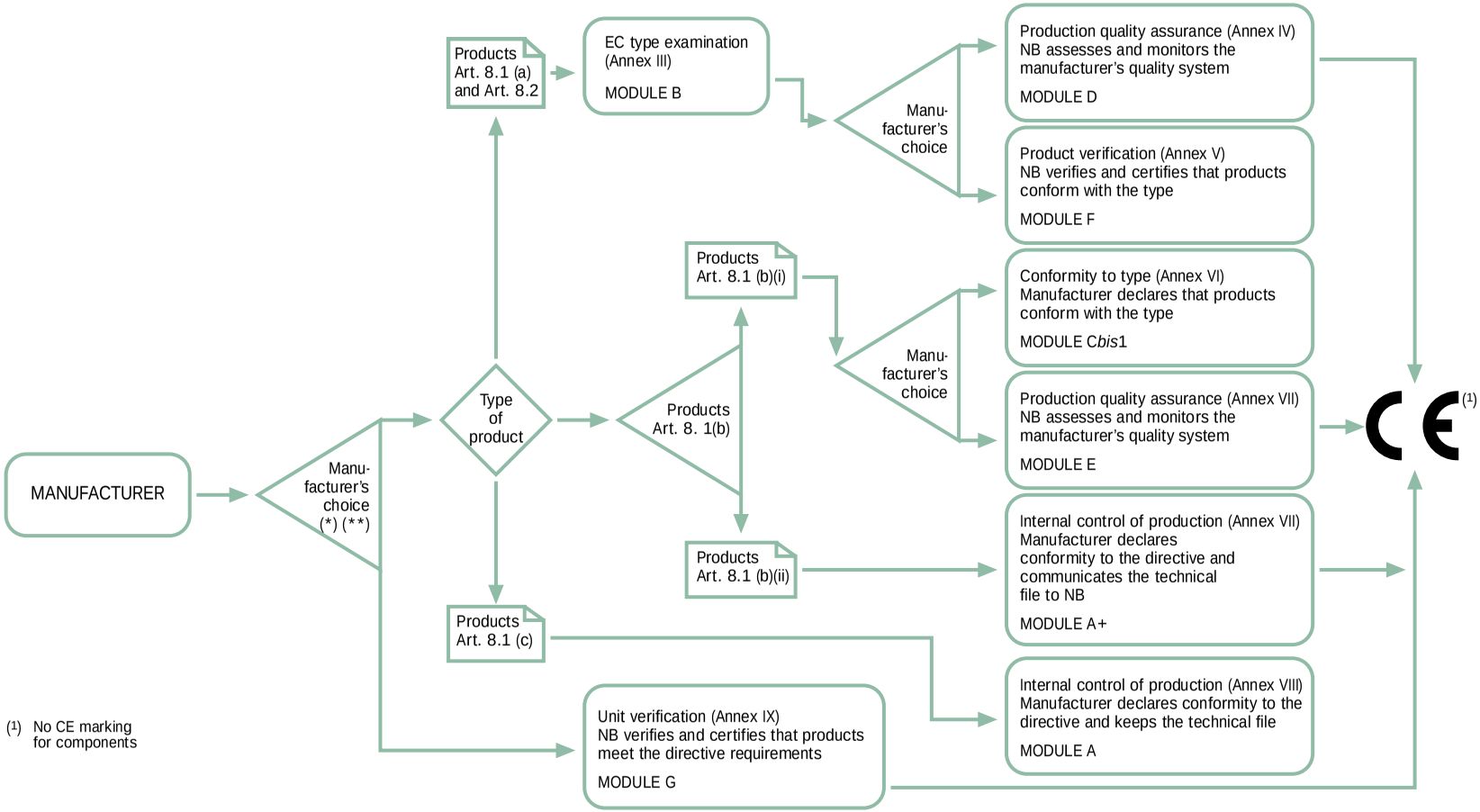
13. Flow chart for the conformity assessment procedures provided for in Directive 94/9/EC on equipment and protective systems intended for use in potential explosive atmospheres



(1) No CE marking for components

(*) All referred procedures shall be applied in respect of components, with the exception of the affixing of the CE marking (Art. 8.3).
(**) Manufacturer may follow the 'internal control of production' (Annex VIII) procedure with regard to the safety aspects referred to in point 1.2.7 of Annex II to the Directive.

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	• 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)	• 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	In addition to the responsibilities as in module A: • 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	In addition to the responsibilities as in module A: • affixes the notified body's identification number to follow the CE marking, if the notified body intervened during the production stage	• 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	As in module A: • applies for product checks at random intervals	In addition to the responsibilities as in module A: • affixes the notified body's identification number to follow the CE marking	• 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	• establishes a technical documentation as regards the design, manufacture and operation of the product	• 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	• 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	• 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)	• 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	
C*bis*1	As in modules C and Aa1	As in modules C and Aa1	As in module Aa1
C*bis*2	As in modules C and Aa2	As in modules C and Aa2	As in module Aa2
D	• 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	• 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	• 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
D*bis*	• 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
E*bis*	As in module D*bis*, but operates an approved quality system for final product inspection and testing	As in module D	As in module D
F	• 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) Where the statistical verification is used: • 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	• 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	• 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
F*bis*	• 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) Where the statistical verification is used: • 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	• 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	• 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	• 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	• 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	• 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
H*bis*	In addition to responsibilities as in module H: • 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: • 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)