10.4. ANNEX 4 – CONFORMITY ASSESSMENT PROCEDURES (MODULES FROM DECISION NO 768/2008/EC)

Modules	Manufacturer	Manufacturer or Authorised representative	Conformity assessment body
A (Internal production control) • Design + Production • The manufacturer carries out himself all checks in order to ensure the conformity of the products to the legislative requirements (no EC-type)	• draws up the technical documentation • ensures compliance of the manufactured products to the legislative requirements	• affixes the CE Marking • draws up a written declaration of conformity and keeps it together with the technical documentation and other relevant information at the disposal of the national authorities	No involvement of conformity assessment body. The manufacturer carries out himself all checks a notified body would do
A1 (Internal production control plus supervised product testing) • Design + Production • A + tests on specific aspects of the product	• draws up the technical documentation • ensures compliance of the manufactured products to the legislative requirements • carries out tests or has tests carried out on his behalf on one or more specific aspects of the product. In this respect and at his choice tests are • 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 under the responsibility of a notified body, he shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process	• affixes the CE Marking • draws up a written declaration of conformity and keeps it together with the technical documentation, the decision of the (notified or in-house accredited) body and other relevant information at the disposal of the national authorities	Either notified body or in-house accredited body (manufacturer's choice)*: A) In-house accredited body • carries out tests on one or more specific aspects of the product • keeps record of its decisions and other relevant information • informs authorities and the other bodies about the examinations it has performed B) Notified Body • supervises and assumes responsibility • for tests carried out by the manufacturer or on his behalf on one or more specific aspects of the product • keeps record of its decisions and other • relevant information • informs authorities and the other bodies about the examinations it has performed
A2 (Internal production control plus supervised product checks at random intervals) • Design + Production • A + product checks at random intervals	• draws up the technical documentation • ensures compliance of the manufactured products to the legislative requirements • lodges an application for product checks with a single body of his choice • where the tests are carried out by a notified body, he shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process	• affixes the CE Marking • draws up a written declaration of conformity and keeps it together with the technical documentation, the decision of the (notified or in-house accredited) body and other relevant information at the disposal of the national authorities	Either notified body or in-house accredited body(manufacturer's choice)*: • carries out product checks at random intervals determined by the body • keeps record of its decisions and other relevant information • informs authorities and the other bodies about the examinations it has performed

Modules	Manufacturer	Manufacturer or Authorised representative	Conformity assessment body
B (EC-type examination) • Design	• draws up the technical documentation • ensures the conformity of the specimen(s) to the legislative requirements • Remark: As module B covers only the design phase, the manufacturer does not draft any declaration of conformity and may not affix the notified body's • identification number to the product	• lodges an application for EC-type examination with a single notified • body of his choice keeps the technical • documentation and the EC-type examination certificate and other relevant information at the disposal of the national authorities • informs the notified body of all modifications to the approved type	Notified Body • examines the technical documentation and supporting evidence. • verifies that the specimen(s) have been manufactured in conformity to the legislative requirements. In this respect, the legislator lays down which of the following ways must be used: • examination of a specimen, (production type); • examination of the technical documentation plus examination of specimen, (combination of production type and design type); • examination of the technical documentation, without examination of a specimen (design type). • carries out appropriate examinations and tests • draws up an evaluation report that may be released only upon agreement with the manufacturer • issues an EC-type examination • certificate • informs its notifying authorities and the other bodies about the EC-type examinations it has performed • keeps record of its decisions and other relevant information
C (Conformity to EC-type based on internal production control) • Production (follows B) • The manufacturer carries out himself all checks to ensure the conformity of the products to the EC-type.	• ensures compliance of the manufactured products to the approved (under module B) EC-type and the legislative requirements	• affixes the CE Marking • draws up a written declaration of • conformity and keeps it together with the technical documentation of the approved type (established under module B) and other relevant information at the disposal of the national authorities	• No involvement of Conformity assessment body. The manufacturer carries out himself all checks a notified body would do

Modules	Manufacturer	Manufacturer or Authorised representative	Conformity assessment body
C1 (Conformity to EC-type based on internal production control plus supervised product testing) • Production (follows B) • C + tests on specific aspects of the product	• ensures compliance of the manufactured products to the approved (under module B) EC-type and the legislative requirements • carries out tests or has tests carried out on his behalf on one or more specific aspects of the product. In this respect and at his choice tests are • 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 under the responsibility of a notified body, he shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process	• affixes the CE Marking • draws up a written declaration of conformity and keeps it together with the technical documentation of the approved type (established under module B), the decision of the (notified or in-house accredited) body and other relevant information at the disposal of the national authorities	Either notified body or in-house accredited body (manufacturer's choice)*: A) In-house accredited body • carries out tests on one or more specific aspects of the product • Remark: the in-house accredited body takes into account the technical documentation but does not examine it, as it has been already examined under module B • keeps record of its decisions and other relevant information • informs authorities and the other bodies about the examinations it has performed B) Notified Body • supervises and assumes responsibility for tests carried out by the manufacturer or on his behalf on one or more specific aspects of the product • Remark: the notified body takes into account the technical documentation but does not examine it, as it has been already examined under module B. • keeps record of its decisions and other relevant information informs authorities and the other bodies about the examinations it has performed
C2 (Conformity to EC-type based on internal production control plus supervised product checks at random intervals) • Production (follows B) • C + product checks at random intervals	• ensures compliance of the manufactured products to approved (under module B) EC-type and the legislative requirements • lodges an application for product checks with a single body of his choice • where the tests are carried out by a notified body, he shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process	• affixes the CE Marking • draws up a written declaration of conformity and keeps it together with the technical documentation of the approved type (established under module B), the decision of the (notified or in-house accredited) body and other relevant information at the disposal of the national authorities	Either notified body or in-house accredited body(manufacturer's choice)*: • carries out product checks at random intervals determined by the body • Remark: the in-house accredited body or notified body takes into account the technical documentation but does not examine it, as it has been already examined under module B • keeps record of its decisions and other relevant information • informs authorities and the other bodies about the examinations it has performed

Modules	Manufacturer	Manufacturer or Authorised representative	Conformity assessment body
D (Conformity to EC-type based on quality assurance of the production process) • Production (follows B) • Quality assurance for manufacturing and inspection of final product	• operates an approved quality system for production, final product inspection and testing of the products in order to ensure compliance of the manufactured products to the approved (under module B) EC-type and the legislative requirements The quality system must include the following elements and has to be documented: quality objectives, organisational structure, manufacturing and quality control techniques, tests (carried out before, during and after manufacturing), quality records, monitoring methods • fulfils the obligations arising out of the quality system • ensures compliance of the manufactured products to approved (under module B) EC-type and the legislative requirements	lodges an application for the assessment of the quality system with a single notified body of his choice • keeps the notified body informed of any change to the quality system • draws up a written declaration of conformity and keeps it together with the technical documentation of the approved type (established under module B), the quality system approval and other relevant information at the disposal of the national authorities • affixes the CE Marking • affixes, under the responsibility of the notified body, the latter's identification number	Notified Body • performs periodic audits in order to assess and survey the quality system Audits include: review of the technical documentation, control of the quality system, inspections, product tests • notifies its decision about the quality assurance system to the manufacturer (the notification shall contain the conclusions of the audit and the reasoned assessment decision) • keeps record of its decisions and other relevant information • informs its notifying authorities and the other bodies about the quality system examinations it has performed
D1 (Quality assurance of the production process) • Design + Production • Quality assurance for manufacturing and inspection of final product • Used like D without module B (No EC-type)	• draws up the technical documentation • operates an approved quality system for production, final product inspection and testing of the products in order to ensure compliance of the manufactured products to the legislative requirements The quality system must include the following elements and has to be documented: quality objectives, organisational structure, manufacturing and quality control techniques, tests (carried out before, during and after manufacturing), quality records, monitoring methods • fulfils the obligations arising out of the quality system • ensures compliance of the manufactured products to the legislative requirements	• lodges an application for the assessment of the quality system with a single notified body of his choice • keeps the notified body informed of any change to the quality system. • draws up a written declaration of conformity and keeps it together with the technical documentation, the quality system approval and other relevant information at the disposal of the national authorities • affixes the CE Marking • affixes, under the responsibility of the notified body, the latter's identification number	Notified Body • performs periodic audits in order to assess and survey the quality system Audits include: review of the technical documentation, control of the quality system, inspections, product tests • notifies its decision about the quality assurance system to the manufacturer (the notification shall contain the conclusions of the audit and the reasoned assessment decision) • keeps record of its decisions and other relevant information • informs its notifying authorities and the other bodies about the quality system examinations it has performed

Modules	Manufacturer	Manufacturer or Authorised representative	Conformity assessment body
E (Conformity to EC-type based on product quality assurance) • Production (follows B) • Final product (=production without the manufacturing part) quality assurance • Like D without the part of the quality system that focuses on the manufacturing process	• operates an approved quality system for final product inspection and testing in order to ensure compliance of the manufactured products to the approved (under module B) EC-type and the legislative requirements The quality system must include the following elements and has to be documented: quality objectives, organisational structure, tests (carried out after the manufacturing), quality records, monitoring methods • Remark: tests carried out before/ during manufacturing, and manufacturing techniques, are not part of the quality system under module E (as it is the case for modules D, D1), because module E targets the final product quality and not the quality of the whole production process (as it is the case for modules D, D1) • fulfils the obligations arising out of the • quality system • ensures compliance of the manufactured products to approved (under module B) EC-type and the legislative requirements	• lodges an application for the assessment of the quality system with a single notified body of his choice • keeps the notified body informed of any change to the quality system • draws up a written declaration of conformity and keeps it together with the technical documentation of the approved type (established under module B), the quality system approval and other relevant information at the disposal of the national authorities • affixes the CE Marking • affixes, under the responsibility of the notified body, the latter's identification number	Notified Body performs periodic audits in order to assess and survey the quality system Audits include: control of the quality system, inspections, product tests Remark: the notified body takes into account the technical documentation but does not examine it, as it has been already examined under module B • notifies its decision about the quality assurance system to the manufacturer (the notification shall contain the conclusions of the audit and the reasoned assessment decision) • keeps record of its decisions and other relevant information • informs its notifying authorities and the other bodies about the quality system examinations it has performed

Modules	Manufacturer	Manufacturer or Authorised representative	Conformity assessment body
E1 (Quality assurance of final product inspection and testing) • Design + Production • Final product (=production without the manufacturing part) quality assurance • Like D1 without the part of the quality system that focuses on the manufacturing process • Used like E without module B (No EC- type)	• draws up the technical documentation • operates an approved quality system for final product inspection and testing in order to ensure compliance of the • manufactured products to the legislative requirements The quality system must include the following elements and has to be documented: quality objectives, organisational structure, tests (carried out after the manufacturing), quality records, monitoring methods • Remark: tests carried out before/ during manufacturing, and manufacturing techniques, are not part of the quality system under module E1 (as it is the case for modules D, D1), because module E1 (like module E) targets the final product quality and not the quality of the whole production process (as it is the case for modules D, D1) • fulfils the obligations arising out of the quality system. • ensures compliance of the manufactured products to the legislative requirements	• lodges an application for the assessment of the quality system with a single notified body of his choice • keeps the notified body informed of any change to the quality system • draws up a written declaration of conformity and keeps it together with the technical documentation, the quality system approval and other relevant information at the disposal of the national authorities • affixes the CE Marking • affixes, under the responsibility of the notified body, the latter's identification number	Notified Body • performs periodic audits in order to assess and survey the quality system Audits include: review of the technical documentation, control of the quality system, inspections, product tests • notifies its decision about the quality assurance system to the manufacturer (the notification shall contain the conclusions of the audit and the reasoned • assessment decision) • keeps record of its decisions and other relevant information • informs its notifying authorities and the other bodies about the quality system examinations it has performed

Modules	Manufacturer	Manufacturer or Authorised representative	Conformity assessment body
F (Conformity to EC-type based on product verification) • Production (follows B) • Product examination (testing of every product or statistical checks) in order to ensure conformity to EC-type • Like C2 but the notified body carries out more detailed product checks.	• ensures compliance of the manufactured products to approved (under module B) EC-type and the legislative requirements • in case where statistical verification is performed, takes all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his products for verification in the form of homogeneous lots	• lodges an application for product checks with a single notified body of his choice • affixes the CE Marking • draws up a written declaration of conformity and keeps it together with the technical documentation of the approved type (established under module B), the certificate of conformity and other relevant information at the disposal of the national authorities • Upon permission of the notified body affixes its identification number	Notified Body • carries out appropriate examinations and tests (testing of every product or statistical checks) • In the scenario of statistical verification and if a lot is rejected, the notified body shall take appropriate measures to prevent that lot's being placed on the market. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures • Remark: the notified body takes into account the technical documentation but does not examine it, as it has been already examined under module B • issues a certificate of conformity • affixes its identification number or delegates to the manufacturer the affixing of its identification number • keeps record of its decisions and other relevant information • informs its notifying authorities and the other bodies about the examinations it has performed
F1 (Conformity based on product verification) • Design + Production • Product examination (testing of every product or statistical checks) in order to ensure conformity to legislative requirements) • Used like F without module B (no EC- type)	• draws up the technical documentation • ensures compliance of the manufactured products to approved (under module B) EC-type and the legislative requirements • in case where statistical verification is performed, takes all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his products for verification in the form of homogeneous lots	• lodges an application for product checks with a single notified body of his choice • affixes the CE Marking • draws up a written declaration of conformity and keeps it together with the technical documentation, the certificate of conformity and other relevant information at the disposal of the national authorities • Upon permission of the notified body affixes its identification number	Notified Body • carries out appropriate examinations and tests (testing of every product or statistical checks) • In the scenario of statistical verification and if a lot is rejected, the notified body shall take appropriate measures to prevent that lot's being placed on the market. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures. • issues a certificate of conformity • affixes its identification number or delegates to the manufacturer the affixing of its identification number • keeps record of its decisions and other relevant information • informs its notifying authorities and the other bodies about the examinations it has performed

Modules	Manufacturer	Manufacturer or Authorised representative	Conformity assessment body
G (Conformity based on unit verification) • Design + Production • Verification of every individual product in order to ensure conformity to legislative requirements (no EC-type)	• draws up the technical documentation • ensures compliance of the manufactured products to the legislative requirements • lodges an application for product checks with a single notified body of his choice	• affixes the CE marking • affixes, under the responsibility of the notified body the latter's identification number • draws up a written declaration of conformity and keeps it together with the technical documentation, the certificate of conformity and other relevant information at the disposal of the national authorities	Notified Body • carries out appropriate examinations • issues a certificate of conformity • keeps record of its decisions and other relevant information • informs its notifying authorities and the other bodies about the examinations it has performed
H (Conformity based on full quality assurance) • Design + Production • Full quality assurance • No EC-type	• draws up the technical documentation • operates an approved quality system for production, final product inspection and testing of the products. • The quality system must include the following elements and has to be documented: quality objectives, organisational structure, manufacturing and quality control techniques, verification techniques for product design, tests (carried out before, during and after manufacturing), quality records, monitoring methods • fulfils the obligations arising out of the quality system • ensures compliance of the manufactured products to the legislative requirements	• lodges an application for the assessment of the quality system with a single notified body of his choice • keeps the notified body informed of any change to the quality system. • draws up a written declaration of conformity and keeps it together with the technical documentation, the quality system approval and other relevant information at the disposal of the national authorities • affixes the CE Marking • affixes, under the responsibility of the notified body, the latter's identification number	Notified Body • performs periodic audits in order to assess and survey the quality system • Audits include: review of the technical documentation, control of the quality system, inspections, product tests • notifies its decision about the quality assurance system to the manufacturer (the notification shall contain the conclusions of the audit and the reasoned assessment decision) • keeps record of its decisions and other relevant information • informs its notifying authorities and the other bodies about the quality system examinations it has performed
H1 (Conformity based on full quality assurance plus design examination) • Design + Production • Full quality assurance plus design examination in order to ensure conformity to legislative requirements • No EC-type but EC-design examination • certificate • Like module H plus issuing of a EC design examination certificate	• draws up the technical documentation • operates an approved quality system for production, final product inspection and testing of the products. • The quality system must include the following elements and has to be documented: quality objectives, organisational structure, manufacturing and quality control techniques, verification techniques for product design, tests (carried out before, during and after manufacturing), quality records, monitoring methods • fulfils the obligations arising out of the quality system • ensures compliance of the manufactured products to the approved EC-de- sign and the legislative requirements	• lodges an application for EC design examination with the same notified body that will assess the quality system • lodges an application for assessment of his quality system with the notified body of his choice • keeps the notified body informed of any modification to the approved de- sign and of any change to the quality system. • draws up a written declaration of conformity and keeps it together with the technical documentation, the EC design examination certificate, the quality system approval and other relevant information at the disposal of the national authorities • affixes the CE Marking • affixes, under the responsibility of the notified body, the latter's identification number	Notified Body • examines the product design • issues an EC design examination certificate • performs periodic audits in order to • assess and survey the quality system • Audits include: review of the technical documentation, control of the quality system, inspections, product tests • notifies its decision about the quality assurance system to the manufacturer (the notification shall contain the conclusions of the audit and the reasoned assessment decision) • keeps record of its decisions and other relevant information • informs its notifying authorities and the other bodies about the quality system and EC-design examinations it has performed

* The legislator may restrict manufacturer's choice