

Form



Product Service

**Application for CE Conformity Assessment (QM)
Application for the certification of a Quality Management System (EN ISO 13485)**

According to Council Directive 93/42/EEC (MDD): Annex II excluding (4) Annex V Annex VI
 According to Council Directive 90/385/EEC (AIMDD): Annex 2 excluding (4) Annex 5
 According to Council Directive 98/79/EC (IVDD): Annex IV excluding (4) and (6) Annex VII

EN ISO 13485:2003 **with** Design and Development
 EN ISO 13485:2003 **without** Design and Development
 EN ISO 13485:2003 **without** Design and Development, Control of production and service provision, Validation of processes for production and service provision

Please send this application to your contact person of Medical Health Services of the TÜV SÜD Group.
 The application will be processed by notified body with number 0123 / certification body according to EN ISO 13485:
 TÜV SÜD PRODUCT SERVICE, Ridlerstraße 65, 80339 MÜNCHEN. Country: Germany.
 Phone: +49 (89) 5008-40; Email: medical_devices@tuev-sued.de; Website: <http://www.tuev-sued.de/ps>

Manufacturer:
(Name and address, contact person; telephone, fax, E-mail)

Authorized EC-representative*:
(Name and address, contact person; telephone, fax, E-mail)

**If EC-representative is applicant please provide power of attorney.*

Design facility(ies):**
(Name and address)

Manufacturing facility(ies):**
(Name and address)

*** Please provide attachment for additional Design facilities or Manufacturing facilities, if necessary.*

Outsourced manufacturing processes (e.g. sterilization):**
(Name and address)

Original Equipment Manufacturer (if applicable):**
(Name and address)

*** Please provide attachment for additional outsourced manufacturing processes, if necessary*

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**Application for CE Conformity Assessment (QM)
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For EC-Directive:

Product category:

Product*:**

Further products listed on attachment.

Applicable Code:

<input type="checkbox"/> UMDNS (AIMDD, MDD):	<input type="text"/>
<input type="checkbox"/> EDMS (IVDD):	<input type="text"/>
<input type="checkbox"/> GMDN (AIMDD, MDD)****:	<input type="text"/>
<input type="checkbox"/> DIMDI Manufacturer Code: [only for manufacturers in Germany]	<input type="text"/>

Classification:

<input type="checkbox"/> MDD I sterile	Rule: <input type="text"/>	<input type="checkbox"/> AIMDD
<input type="checkbox"/> MDD I measuring function	Rule: <input type="text"/>	
<input type="checkbox"/> MDD I sterile/ measuring function	Rule: <input type="text"/>	<input type="checkbox"/> IVDD, List A
<input type="checkbox"/> MDD IIa	Rule: <input type="text"/>	<input type="checkbox"/> IVDD, List B
<input type="checkbox"/> MDD IIb	Rule: <input type="text"/>	<input type="checkbox"/> IVDD, Self-testing (<i>but not glucose</i>)
<input type="checkbox"/> MDD III	Rule: <input type="text"/>	

**:

***:

****:

Please provide attachment for additional facilities, if necessary.

Please provide attachment for additional products, if necessary.

Please provide additional information needed for MDD:
for class IIa devices: for each device subcategory scope expression by NBOG BPG 2009-3,
for class IIb devices: generic device group(s) referenced by GMDN preferred term(s).

Attachment:

- A general description of the product(s) including the intended use are attached.
- Copy(ies) of the MDD EC-Type Examination Certificate(s) (for Annex V or Annex VI in combination with either class IIb or class III products by TÜV SÜD Product Service GmbH), for EC related procedures only, and if the certificates have not been issued by TÜV SÜD Product Service GmbH, for EC related procedures only.
- Copy(ies) der IVDD EG-Type-Examination Certificate(s) (for Annex VII in combination with product(s) as of Annex II List A or B, and only, if the certificate(s) have not been issued by TÜV SÜD Product Service GmbH, for EC related procedures only.
- EC-representative's power of attorney for EC-representation (if applicant).

Scope of EN ISO 13485 Certificate*:

*: In case applicant provides services to other organizations, e.g. sterilization, maintenance, installation (...), please add a general description of services provided.

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At stage of application for conformity assessment of a Quality System according to the Directive(s) the undersigned confirms,

- that no application has been lodged with any other notified body for the same products,
- to send copies of reports of Field Safety Corrective Actions (recalls) and Field Safety Notices (FSN) to the Notified Body TÜV SÜD Product Service GmbH,
- that he will inform the Notified Body TÜV SÜD Product Service GmbH having approved the quality system of any plan for substantial changes to the quality system or the product-range covered.
- that the business relations are based on the Standard Terms and Conditions as well as Testing and Certification Regulations of TÜV SÜD Product Service GmbH in their most current version. In the event of certification the applicant will automatically become a member of the certification system of TÜV SÜD Product Service GmbH - if this is not already the case,
- acceptance of and conformity with all the undertakings contained in the parts of the directives which are applicable for this product / product group and / or EN ISO 13485 and especially with the points in the Attachment 1 of this application MED_F_0304.01.

At stage of application for the certification of a Quality system according to the EN ISO 13485 the undersigned confirms,

- to fulfill the obligations resulting from the Quality Management System certified,
- to maintain the Quality Management System to assure its adequacy and effectiveness,
- that the business relations are based on the Standard Terms and Conditions as well as Testing and Certification Regulations of TÜV SÜD Product Service GmbH in their most current version. In the event of certification the applicant will automatically become a member of the certification system of TÜV SÜD Product Service GmbH - if this is not already the case,
- to the best of his knowledge that all data and information related to this application are true and accurate and no material fact has been omitted.

If [legal] manufacturer signs this application please use this left column ↓	If EC-Representative signs this application please use this right column ↓
Name of company representative:	Name of EC-Representative: (In case application is submitted by EC-Representative)
Signature:	Signature:
Date:	Date:
Company seal:	Company seal:

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Attachment 1

The undersigned of the application confirms (this is valid for all directives and conformity assessment routes as mentioned in the application),

- to notify the competent authorities of the following incidents immediately on learning of them:
 - (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling and instructions for use which might lead to or might have led directly or indirectly to the death or to a serious deterioration in the state of health of a patient, user, or any other person;
 - (ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.
- that the products meet the applicable requirements of the directive 90/385/EEC (AIMDD) and/or the directive 93/42/EEC (MDD) and/or the directive 98/79/EC (IVDD) and fulfill, based on continuous assessments of complaints, the manufacturing specifications in relation to the usability.
- to the best of his knowledge, that all data and information related to this application are true and accurate and no material fact has been omitted.
- if TÜV SÜD marks are used these marks shall not be used on a product or product packaging seen by the consumer or in any other way that may be interpreted as denoting product conformity.
- not to apply TÜV SÜD marks to laboratory test, calibration or inspection reports as such reports are deemed to be products in this context.
- that he conforms to the requirements of the certification body when making reference to its certification status in communication media such as the internet, brochures or advertising, or other documents.
- that he does not make or permit any misleading statement regarding its certification.
- that he does not use or permit the use of a certification document or any part thereof in a misleading manner.
- that upon suspension or withdrawal of its certification, he discontinues its use of all advertising matter that contains a reference to certification, as directed by the certification body.
- that he amends all advertising matter when the scope of certification has been reduced.
- that he does not allow reference to its management system certification to be used in such a way as to imply that the certification body certifies a product (including service) or process.
- that he does not imply that the certification applies to activities that are outside the scope of certification.
- that he does not use its certification in such a manner that would bring the certification body and/or certification system into disrepute and lose public trust.
- that he fulfills all the applicable parts of the directives. Most important parts (despite the essential requirements Annex I / Annex 1) with reference to the different conformity assessment routes are mentioned below:

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Product Service

MDD, Annex II excluding (4):

EC DECLARATION OF CONFORMITY (Full quality assurance system)

- 1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3 and is subject to audit as laid down in Sections 3.3 and 4 and to Community surveillance as specified in Section 5.
- 2. The EC declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer.

3. Quality system

- 3.1 The manufacturer must lodge an application for assessment of his quality system with a notified body. The application must include:
 - the name and address of the manufacturer and any additional manufacturing site covered by the quality system,
 - all the relevant information on the product or product category covered by the procedure,
 - a written declaration that no application has been lodged with any other notified body for the same product-related quality system,
 - the documentation on the quality system,
 - an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,
 - an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,
 - an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:
 - (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
 - (ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.
- 3.2 Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records. It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c). It shall include in particular an adequate description of:
 - (a) the manufacturer's quality objectives;
 - (b) the organization of the business and in particular:
 - the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,
 - the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform,
 - where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;
 - (c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular:
 - a general description of the product, including any variants planned, and its intended use(s),

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- the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full,
 - the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed,
 - if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,
 - a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,
 - a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC (1),
 - the solutions adopted as referred to in Annex I, Chapter I, Section 2,
 - the pre-clinical evaluation,
 - the clinical evaluation referred to in Annex X,
 - the draft label and, where appropriate, instructions for use.
- (d) the inspection and quality assurance techniques at the manufacturing stage and in particular:
- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
 - the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
- (e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately.

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Product Service

MDD, Annex V:

EC DECLARATION OF CONFORMITY (Production quality assurance)

- 1. The manufacturer must ensure application of the quality system approved for the manufacture of the products concerned and carry out the final inspection, as specified in Section 3, and is subject to the Community surveillance referred to in Section 4.
- 2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them. The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and must be kept by the manufacturer.

3. Quality system

- 3.1 The manufacturer must lodge an application for assessment of his quality system with a notified body. The application must include:
 - the name and address of the manufacturer,
 - all the relevant information on the product or product category covered by the procedure,
 - a written declaration that no application has been lodged with any other notified body for the same products,
 - the documentation on the quality system,
 - an undertaking to fulfil the obligations imposed by the quality system is approved,
 - an undertaking to maintain the practicability and effectiveness of the approved quality system,
 - where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates,
 - an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:
 - (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
 - (ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) above leading to a systematic recall of devices of the same type by the manufacturer.
- 3.2 Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.

It must include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c).

It must include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

- the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,
- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of products which fail to conform,
- where the manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

(c) the inspection and quality assurance techniques at the manufacturing stage and in particular:

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- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
 - the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
- (d) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.

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MDD, Annex VI:

EC DECLARATION OF CONFORMITY (Product quality assurance)

- 1. The manufacturer must ensure application of the quality system approved for the final inspection and testing of the product, as specified in Section 3 and must be subject to the surveillance referred to in Section 4.
- 2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.
The manufacturer affixes the CE marking in accordance with Article 17 and draws up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and be kept by the manufacturer. The CE marking must be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex..

3. Quality system

- 3.1 The manufacturer lodges an application for assessment of his quality system with a notified body.
The application must include:
 - the name and address of the manufacturer,
 - all the relevant information on the product or product category covered by the procedure,
 - a written declaration that no application has been lodged with any other notified body for the same products,
 - the documentation on the quality system,
 - an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,
 - an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,
 - where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates,
 - an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:
 - (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
 - (ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to a systematic recall of devices of the same type by the manufacturer.
- 3.2 Under the quality system, each product or a representative sample of each batch is examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests are carried out to ensure that the products conform to the type described in the EC type-examination certificate and fulfil the provisions of this Directive which apply to them. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must permit uniform interpretation of the quality programmes, quality plans, quality manuals and quality records.
It must include in particular an adequate description of:
 - the quality objectives and the organizational structure, responsibilities and powers of the managerial staff with regard to product quality,
 - the examinations and tests that will be carried out after manufacture; it must be possible to trace back the calibration of the test equipment adequately,
 - the methods of monitoring the efficient operation of the quality system,
 - the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.,
 - where the final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party.The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

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AIMDD, Annex 2 excluding (4):

EC DECLARATION OF CONFORMITY (Complete quality assurance system)

- 1. The manufacturer shall apply the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3 and is subject to EC surveillance as specified in Section 5.
- 2. The declaration of conformity is the procedure by means of which the manufacturer who satisfies the obligations of Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

The manufacturer or this authorized representative established within the Community shall affix the CE marking in accordance with Article 12 and shall draw up a written declaration of conformity.

This declaration shall cover one or more clearly identified devices by means of product name, product code or other unambiguous reference and must be kept by the manufacturer.

The CE marking shall be accompanied by the identification number of the notified body responsible.

3. Quality system

- 3.1 The manufacturer shall make an application for evaluation of his quality system to a notified body. The application shall include:
 - all the appropriate items of information for the category of products manufacture of which is envisaged,
 - the quality-system documentation,
 - an undertaking to fulfil the obligations arising from the quality system as approved,
 - an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,
 - an undertaking by the manufacturer to institute and keep updated a post-market surveillance system including the provisions referred to in Annex 7. The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:
 - (i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health;
 - (ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.
- 3.2 The application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final controls. All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records. It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c). It shall include in particular an adequate description of:
 - (a) the manufacturer's quality objectives;
 - (b) the organization of the business and in particular:
 - the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,
 - the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the design and of the products, including control of products which do not conform,
 - where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;
 - (c) the procedures for monitoring and verifying the design of the products and in particular:

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- the design specifications, including the standards which will be applied and a description of the solutions adopted to fulfil the essential requirements which apply to the products when the standards referred to in Article 5 are not applied in full,
 - the techniques of control and verification of the design, the processes and systematic actions which will be used when the products are being designed,
 - a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in Section 10 of Annex 1 and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,
 - the pre-clinical evaluation,
 - the clinical evaluation referred to in Annex 7;
- (d) the techniques of control and of quality assurance at the manufacturing stage and in particular:
- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
 - product-identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
- (e) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.

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AIMDD, Annex 5:

EC DECLARATION OF CONFORMITY TO TYPE (Assurance of production quality)

- 1. The manufacturer shall apply the quality system approved for the manufacture and shall conduct the final inspection of the products concerned, as specified in 3; he shall be subject the surveillance as referred to in Section 4.
- 2. This declaration of conformity is the procedural element whereby the manufacturer who satisfies the obligations of section 1 guarantees and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of the Directive which apply to them.
The manufacturer or his authorized representative established within the Community shall affix the CE marking in accordance with Article 12 and draw up a written declaration of conformity. This declaration shall cover one or more devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer. The CE marking shall be accompanied by the identification number of the notified body responsible.

3. Quality system

- 3.1 The manufacturer shall make an application for evaluation of his quality system to a notified body.
The application shall include:
 - all the appropriate information concerning the products which it is intended to manufacture,
 - the quality-system documentation,
 - an undertaking to fulfil the obligations arising from the quality system as approved,
 - an undertaking to maintain the approved quality system in such way that it remains adequate and efficacious,
 - where appropriate, the technical documentation on the types relating to the approved type and a copy of the EC type-examination certificate,
 - an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system including the provisions referred to in Annex 7. The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:
 - (i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or led to the death of a patient or a deterioration in his state of health;
 - (ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.
- 3.2 Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.
All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records.
It shall include in particular an adequate description of:
 - (a) the manufacturer's quality objectives;
 - (b) the organization of the business and in particular:
 - the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,
 - the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the products, including control of products which do not conform,
 - where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;
 - (c) the techniques of control and quality assurance at the manufacturing stage and in particular:
 - the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
 - the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
 - (d) the appropriate tests and trials which will be affected before, during and after production, the frequency with which they will take place, to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used.

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IVDD, Annex II excluding (4) and (6):

EC DECLARATION OF CONFORMITY (FULL QUALITY ASSURANCE SYSTEM)

- 1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the devices concerned, as specified in section 3, and is subject to audit as laid down in section 3.3 and to the surveillance as specified in section 5. In addition, the manufacturer must follow, for devices covered by Annex II, List A, the procedures laid down in sections 4 and 6.
- 2. The EC declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them. The manufacturer shall affix the CE marking in accordance with Article 16 and shall draw up a declaration of conformity covering the devices concerned.

3. Quality system

- 3.1 The manufacturer must lodge an application for assessment of his quality system with a notified body. The application must include:
 - the name and address of the manufacturer and any additional manufacturing site covered by the quality system,
 - adequate information on the device category covered by the procedure,
 - a written declaration that no application has been lodged with any other notified body for the same device-related quality system,
 - the documentation on the quality system,
 - an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,
 - an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,
 - an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action and notification as referred to in Annex III, section 5.
- 3.2 Application of the quality system must ensure that the devices conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality programmes, quality plans, quality manuals and quality records. It shall include in particular an adequate description of:
 - (a) the manufacturer's quality objectives;
 - (b) the organisation of the business and in particular:
 - the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of design and manufacture of the devices is concerned,
 - the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of devices which fail to conform;
 - (c) the procedures for monitoring and verifying the design of the devices and in particular:
 - a general description of the device, including any variants planned,
 - all documentation referred to in Annex III, section 3, indents 3 to 13,
 - in the case of devices for self-testing, the information referred to in Annex III, section 6.1,
 - the techniques used to control and verify the design and the processes and systematic measures which will be used when the devices are being designed;
 - (d) the inspection and quality assurance techniques at the manufacturing stage and in particular:
 - the processes and procedures which will be used, particularly as regards sterilisation,
 - the procedures in relation to purchasing,
 - the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
 - (e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration.

The manufacturer shall carry out the required controls and tests according to the latest state of the art. The controls and tests shall cover the manufacturing process including the characterisation of the raw material and the individual devices or each batch of devices manufactured.

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Product Service

In testing the devices covered by Annex II, List A, the manufacturer shall take into account the most recent available information, in particular as regards the biological complexity and variability of the specimens to be tested with the *in vitro* device concerned.

IVDD, Annex VII:

EC DECLARATION OF CONFORMITY (PRODUCTION QUALITY ASSURANCE)

- 1. The manufacturer must ensure application of the quality system approved for the manufacture of the devices concerned and carry out the final inspection, as specified in Section 3, and is subject to the surveillance referred to in Section 4.
- 2. The declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.

The manufacturer must affix the CE marking in accordance with Article 16 and draw up a declaration of conformity covering the devices concerned.

3. Quality system

- 3.1 The manufacturer must lodge an application for assessment of his quality system with a notified body.
 - The application must include:
 - the technical documentation of the types approved and a copy of the EC type-examination certificates.
- 3.2 Application of the quality system must ensure that the devices conform to the type described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records. It must include in particular an adequate description of:

 - (a) the manufacturer's quality objectives;
 - (b) the organisation of the business and in particular:
 - the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of manufacture of the devices is concerned,
 - the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of devices which fail to conform;
 - (c) the inspection and quality assurance techniques at the manufacturing stage and in particular:
 - the processes and procedures which will be used, particularly as regards sterilisation,
 - the procedures in relation to purchasing,
 - the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
 - (d) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration.

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Product Service

IVDD, Annex VI:

EC VERIFICATION

- 1. EC verification is the procedure whereby the manufacturer or his authorised representative ensures and declares that the products which have been subject to the procedure set out in section 4 conform to the type described in the EC type-examination certificate and meet the requirements of this Directive which apply to them.
- 2.1 The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the EC type-examination certificate and the requirements of the Directive which apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilisation and the suitability of starting materials, where necessary, and define the necessary testing procedures according to the state of the art. All the routine, pre-established provisions must be implemented to ensure homogeneous production and conformity of the products with the type described in the EC type-examination certificate and with the requirements of this Directive which apply to them.
- 2.2 To the extent that for certain aspects the final testing according to section 6.3 is not appropriate, adequate process testing, monitoring and control methods shall be established by the manufacturer with the approval of the notified body. The provisions of Annex IV, section 5, shall apply accordingly in relation to the abovementioned approved procedures.
- 3. The manufacturer must undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective and notification action as referred to in Annex III, section 5.
- 4. The notified body must carry out the appropriate examinations and tests taking account of section 2.2 in order to verify the conformity of the product with the requirements of the Directive either by examining and testing every product as specified in section 5 or by examining and testing products on a statistical basis as specified in section 6, as the manufacturer decides. When carrying out statistical verification according to section 6, the notified body has to decide when statistical procedures for lot-by-lot inspection or isolated lot inspection have to be applied. Such decision must be taken in consultation with the manufacturer.
In as far as the conduct of examinations and tests on a statistical basis is not appropriate, examinations and tests may be carried out on a random basis provided that such procedure in conjunction with the measures taken in accordance with section 2.2 ensures an equivalent level of conformity.
- **5. Verification by examination and testing of every product**
 - 5.1 Every product is examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out in order to verify the conformity of the products with the EC type described in the type-examination certificate and with the requirements of the Directive which apply to them.
 - 5.2 The notified body must affix, or have affixed, its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.
- **6. Statistical verification**
 - 6.1 The manufacturer must present the manufactured products in the form of homogeneous batches.
 - 6.2 One or more random samples, as necessary, are taken from each batch. The products which make up the sample are examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the EC type-examination certificate and with the requirements of the Directive which apply to them in order to determine whether to accept or reject the batch.
 - 6.3 Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling scheme will be established by the harmonised standards referred to in Article 5, taking account of the specific nature of the product categories in question.

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6.4. If the batch is accepted, the notified body affixes, or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If the batch is rejected the competent notified body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

The manufacturer may, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.