

# Form



Product Service

## Application for CE Conformity Assessment (QM) Application for the certification of a Quality Management System (ISO 13485:2003)

- According to
- ISO 13485:2003 with Design and Development
  - ISO 13485:2003 without Design and Development
  
  - Council Directive 93/42/EEC (MDD), Annex II, Item 3
  - Council Directive 93/42/EEC (MDD), Annex V, Item 3
  - Council Directive 93/42/EEC (MDD), Annex VI, Item 3
  
  - Council Directive 90/385/EEC (AIMDD), Annex 2, Item 3
  - Council Directive 90/385/EEC (AIMDD), Annex 5, Item 3
  
  - Council Directive 98/79/EC (IVDD), Annex IV, Item 3
  - Council Directive 98/79/EC (IVDD), Annex VII, Item 3

to the **Notified Body Reg. No. 0123**, TÜV PRODUCT SERVICE GmbH, **Certification Body**, Ridlerstraße 65, D-80339 München, Tel. +49/ 89/ 500 8 - 4477; Fax +49/ 89/ 500 8 - 4327.

**Manufacturer:**  
*(name and address, contact person; telephone, fax or e-mail)*

**Authorized EC-representative:**  
*(name and address, contact person; telephone, fax or e-mail)*

**Design facility(ies)\*:**  
*(name and address)*

**Manufacturing facility(ies)\*:**  
*(name and address)*

**For EC-Directive:**

**Product category:**

**Product\*\*:**

- Further products listed on attachment:

**Applicable Code:**

- UMDNS (AIMD, MDD) :
- EDMS (IVDD):
- GMDN (optional):

**Classification:**

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

**For ISO 13485:**

**Scope of Certificate:**

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### Attachment:

- A general description of the product(s) including the intended use are attached
- Copy of the MDD/AIMDD EC-Type Examination Certificate(s) (for Annex V or Annex VI in combination with either class IIb or class III products or active implants, and if the certificates have not been issued by TÜV PRODUCT SERVICE GmbH)
  
- Copy of the IVDD EC-Type Examination Certificate(s) (for Annex VII in combination with either Annex II List A products or Annex II List B products, and if the certificates have not been issued by TÜV PRODUCT SERVICE GmbH)
- EC-representative's power of attorney for EC-representation (if applicant)

\* Please provide attachment for additional facilities, if necessary  
\*\* Please provide attachment for additional products, if necessary

The undersigned declares:

- that this application has not been made to any other Notified Body.
  - to fulfill the obligations arising from the quality system as approved.
  - to maintain the approved quality system in such way that it remains adequate and effective.
  - to inform the Notified Body, TÜV PRODUCT SERVICE GmbH, of any plan for substantial changes to the quality system.
  - 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.
  - the Quality System Documentation will be submitted according to the requirements of the Directive(s) within the scope of the TÜV PRODUCT SERVICE GmbH Testing and Certification Regulations for the review of a Quality System.
  - 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.
- TÜV PS is to be informed if the incident possibly occurred in connection with the design and/ or production of the affected product.
- that the business relations are based on the Standard Terms and Conditions as well as Testing and Certification Regulations of TÜV Product Service in their most current version. In the event of certification the applicant will automatically become a member of the certification system of TÜV Product Service - 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.

Date: \_\_\_\_\_

Name of company representative: \_\_\_\_\_

Signature of representative: \_\_\_\_\_

Company seal: