



APPLICATION

FOR PRODUCT ASSESSMENT ACCORDING TO THE COUNCIL DIRECTIVE
No. 93/42/EEC (ADOPTED BY THE GOVERNMENT REGULATION No. **336/2004/CoII.**^{*)})
AND FOR OTHER SERVICES CONNECTED WITH CONFORMITY ASSESSMENT OF
MEDICAL DEVICES

Registration number of SZÚ (*do not complete*)

1. The application has been submitted by (the Customer):

Manufacturer Authorized representative _____ (*trade name*)
 Importer

Street, No. _____ Town: _____

ZIP Code: _____ Country: _____

Contact person: _____ Tel: _____ Fax: _____

E-mail: _____ ID: _____ VAT No.: _____

Bank: _____ Account: _____

The Customer has has not any registered office, place of business or premises in the Czech Republic.
The Customer has has not registered office in the EU.

2. Product (*name, trade name, type designation*):

Derived variants: _____

Manufacturer (*shall be completed by the authorized representative*): _____ OEM¹ OBL²

¹ referred to in Art. 1 Cl. 2. Char. f) of the Council Directive No. 93/42/EEC (hereinafter referred to as "Directive")

² "Own brand labeling" is an expression for the Manufacturers who put already certified products of other OEMs onto single EU market with valid conformity assessment certification under their own brand.

Production site: _____ Outsourced

Classification (Art. 9 of the Directive and Annex IX) I) Is Im IIa IIb III

Note: Class Is - sterile, Im - with a measuring function (Annex VII, Cl. 5)

Categorization according to the nomenclature (optional):

GMDN UMDNS GOST R 51609-2000 codes:
 other: _____

Attach figures, instructions and/or other documentation characterizing the product from the point of view necessary for the required activity. The content of the technical documentation necessary for conformity assessment depends on the chosen procedure according to Annexes II to VII of the Directive. In particular, it is necessary to present declarations whether the medical device incorporates and/or does not incorporate substances shown (Page 3, Clause 11).

Medical device categorization on the basis of production technology and content used:

- | | |
|--|--|
| <input type="checkbox"/> manufactured in sterile condition | <input type="checkbox"/> utilizing micromechanics |
| <input type="checkbox"/> being wholly or mainly absorbed | <input type="checkbox"/> utilizing nanomaterials |
| | <input type="checkbox"/> utilizing biological active coatings and/or materials |

3. The Customer declares:

- that it will meet all requirements for certification and provide all information necessary for the assessment of products that are to be certified,
- that it was made familiar with the product certification system and its rights and obligations
- that it has not submitted and will not upon the completion of the job activities submit the application for product certification or an order for the same activity within the conformity assessment process with another entity.

The product has has not been placed on the EU single market.

4. The Customer applies for the following activities from the Notified Body according to Art. 11 and Art. 12 of the Directive (mark the required activities with a cross)

- 4.1 EC declaration of conformity** (full quality assurance system) according to Annex II of the Directive - examination of the design of the product followed by issue of the EC design-examination certificate (applies only to Class III), quality system assessment and audit performance followed by issue of the assessment report
- 4.2 EC type-examination** according to Annex III of the Directive followed by issue of the EC type-examination certificate (applies to Classes IIb and III only)
- 4.3.1 EC verification** according to Annex IV of the Directive - verification of conformity of each medical device with the type (applies to Classes IIb and III only) described in the EC type-examination certificate followed by issue of the certificate of conformity
- 4.3.2 EC verification** according to Annex IV of the Directive - statistical verification of conformity of a randomly chosen sample(s) with the type (applies to Classes IIb and III only) described in the EC type-examination certificate followed by issue of the certificate of conformity
- 4.4 EC declaration of conformity** (production quality assurance) according to Annex V of the Directive - quality system assessment and audit performance followed by issue of the assessment report
- 4.5 EC declaration of conformity** (medical device quality assurance) according to Annex VI of the Directive - quality system assessment and audit performance followed by issue of the assessment report

5. The Customer applies for the following activities from Strojírenský zkušební ústav (Enginnering Test Institute): *(outside the scope of the Notified Body)*

- 5.1 Assessment, testing and verification of the medical device** folowed by issue of the test report - according to Annex VII, Point 3, of the Government Regulation
- 5.2 Assesment of conformity of the medical device of Class I or IIa** with the essential requirements of the Directive and attestation of conformity by issue of the certificate
- 5.3 Issue of:** certificates
Language: Czech English German Russian French
- 5.4 Issue of:** final (summary) report
Language: Czech English German Russian French
- 5.5 Other (specify):** _____
-
-
-

6. Has the product been tested?

- yes *(attach a copy of the test protocol)* no

7. Has the product been already certified according to the Directive?

- yes *(attach copies of assessment – EC certificate, appr. EC design-examination certificate)* no

8. Has the Manufacturer's quality system been certified?

- yes *(attach a copy of the assessment records)* no

9. Spare documentation shall be

- returned discarded

10. Intended countries of destination: _____

- 11. The Customer declares:** that the medical device does not contain as an integral part:
 human blood or its derivatives³ medicine⁴ animal tissue or its derivatives⁵

If the substance is contained, fill in the particulars: _____

Within the meaning of a provision of Council Directive No. ³ 2000/70/EC as amended by 2001/104/EC; ⁴ 2001/83/EC as amended; ⁵ 2003/32/EC as amended.

- 12. The Customer declares:** that the medical device does not contain as an integral part:
 phthalates⁶ PFOS (perfluorooctansulfonates)⁷

If the substance is contained, fill in the particulars: _____

Within the meaning of a provision of Council Directive No. ⁶ 67/548/EHS as amended; ⁷ 2006/122/ES as amended.

13. The Customer declares: that the medical device and its intended purpose

does not match the definition for:

machinery ⁸

personal protective equipment ⁹

If the definition matches, fill in the particulars:

Within the meaning of a provision of Council Directive No. ⁶ 2006/42/EC as amended; ⁷ 89/686/EEC as amended.

14. The Guarantees and commitments - in case of ordering one of the procedures pursuant to Annex II, Annex V, Annex VI

- the Manufacturer commits to meet the requirements arising from the approved quality system,
- the Manufacturer guarantees to maintain the quality system on an adequate and effective level
- the Manufacturer undertakes to establish and update a systematic procedure of assessing the experience gained in the production of medical devices, including those listed in Annex 10 hereto, and to take appropriate corrective measures; this commitment also involves the Manufacturer's obligation to notify the Institute immediately of all undesirable events under the act on medical devices ¹⁰.

¹⁰ Article 10 of the Council Directive No. 93/42/EEC;

The relationship between the Customer and Strojirenský zkušební ústav (Engineering Test Institute - the Executor) is a contractual relationship. Upon acceptance of the application, the Executor will provide the Customer with a draft contract regarding performance of the activities applied.

The application was completed by:

*name and title
of the responsible person*

date

signature, stamp