

Filled by TSÚ Piešťany, š. p.
Date of receipt:

Application No.

for testing in accordance with requirements on

 ELECTROMAGNETIC COMPATIBILITY (EMC) BASIC SAFETY

of the medical device

1. APPLICANT:**Trade name:****Address:****ID:**

Registered in Companies Register (position, number):

Contact person:

(name, position)

Tel:**Fax:****E-mail:****Bank:****IBAN:****VAT No.:****Authorized representative:**

(name, position)

Tel:**Fax:****E-mail:****Account No.:****SWIFT:****2. PRODUCER: (DO NOT FILL IN IF THE CUSTOMER IS THE PRODUCER)****Trade name:****Address:****ID:**

Registered in Companies Register (position, number):

Contact person:

(name, position)

Tel:**Fax:****E-mail:****Bank:****IBAN:****VAT No.:****Authorized representative:**

(name, position)

Tel:**Fax:****E-mail:****Account No.:****SWIFT:****3. PRODUCT:****Product trade name:****Type:****Derived types (variants):****Classification:** Class I Class IIa Class IIb Class III

(according to Directive 93/42/EEC)

4. THE CUSTOMER APPLIES FOR FOLLOWING ACTIVITIES OF THE TESTING BODY:

- Tests of electromagnetic compatibility of medical device in the range specified by the customer in point 5.
- Tests of basic safety of medical device in the range specified by the customer in point 5.
- Issue of Test Report (-s) in English language
- Other services (please specify):

5. SPECIFICATION OF THE RANGE OF TESTING:

A/ TESTS OF ELECTROMAGNETIC COMPATIBILITY:

standard:

B/ TESTS OF BASIC SAFETY:

standard:

6. ACCOMPANYING DOCUMENTS:

Technical documentation (user manual, risk analysis, production label of the device ...).

List of legislation valid for the product and manufacture.

Other documents (e.g. QMS certificates, certificates of delivery of input materials).

Copy of the Abstract of the Companies Register or business licence.

If the applicant is different from the producer, powers of representation for the purposes of testing of the product.

7. APPLICANT'S DECLARATION ABOUT THE PRODUCT TYPE:

The development of the product as a type was finished and the data provided in this application, the submitted technical documentation and other data are complete and reflect the state of the product at the date of this application.

8. APPLICANT'S DUTIES:

Provide the necessary documentation to perform product tests in the Slovak or English language referred to in point 6.

Submit the sample for testing within the specified time.

Ensure co-operation by product tests to the extent required by the testing body.

9. TRADE AND LEGAL RELATIONSHIP

All trade and legal relationships shall be governed by valid General Trading Conditions of TSÚ Piešťany, š.p. placed at the TSU website <http://www.tsu.en>.

Remarks to the filling of the application form:

The application is to be filled in separately for each type of product, in the case of several product types, the individual types shall be given in point 3 of this application. If a limited space is insufficient when filling in the application, proceed to a separate annex. Accompanying documents under Part 6, which concern at the same time several products required for product tests, are sufficient to accompany one application and make a reference in other applications. Please send your application and accompanying documents in one copy, by e-mail to **obchodne@tsu.sk** or by registered mail at the address given in the header of the application. Accompanying documents must be delivered at the latest at the time of the sample delivery. The sample will be taken for testing only if the required documentation has been supplied with it.

Place:

Date:

Name of the authorized representative:

Signature:

Stamp of the applicant