APPLICATION FOR MEDICAL DEVICES (MD) CONFORMITY ASSESSMENT

according to the Article No. 11 of the Directive 93/42/EEC as amended

No.: | | | | | | | | | |

TIC's Registry Number (do not fill in)

APPLICANT:

Company name:	VAT No.:	
	Registration No.:	
	Registered at:	
Address:	Phone:	
	Fax:	
PIN Code:	e-mail:	@
Banking with:	Account No.:	
Represented by:		
Contact person authorized to conduct negotiations:		

PRODUCT(s):

Name of the Medical Device:	**Product Class:** ☐ **I** ☐ **IIa** ☐ **IIb** ☐ **III**
Type/Model – please write the more detailed specifications on the page 2:	
The medical device contains as an integral part a human blood derivative:	☐ yes ☐ no
Manufacturer's company name and address (if it differs from the applicant):	
Is your company part of some larger organisation? (if yes, specify its name):	☐ yes ☐ no

SPECIFICATION OF THE CONFORMITY ASSESSMENT PROCEDURE:

The chosen conformity assessment procedure according to 93/42/EEC Directive (please, check off the appropriate box)	☐ Annex II	Full quality assurance system
	☐ Annex V	Production quality assurance
	☐ Annex VI	Product quality assurance
	☐ An. III+IV	EC type examination + Verification
	☐ An. III+V	EC type exam. + Production Q.A.
	☐ An. III+VI	EC type exam. + Product Q.A.
	☐	Another requirement (please, specify):
Required language versions of issued certificates:	☐ English ☐ other ( )	

Applicant's declaration:

1. *We agree that product samples will not be returned after assessment.*
2. *We declare that we did not submit similar application for the same product to any other notified body.*
3. *We agree with the "Obligatory Business Conditions" of TIC and we will abide by them.*

....

Date of Application — Stamp and signature of applicant's authorized representative

Detailed specification of the Medical Device (MD) submitted to conformity assessment*:*

Name and description of the product:	
List of documentation enclosed (*figures, drawings, instruction for use & installation, technical specification etc.*) as specified in the Annexes of the 93/42/EEC directive as amended:	
Intended use of the product (*detailed description*):	
Has been this Medical Device placed on the market already? If yes, when has been the Medical Device introduced on the market: If yes, which countries have been the Medical Device placed on the market in?	☐ Yes ☐ No In year
Is the device designed and manufactured in a controlled quality system? If yes, which standards does comply the quality system with?	☐ Yes ☐ No ISO 9001:2008 / ISO 13485:2003
Is the quality system certified?	☐ Yes ☐ No
Are the test reports of the accredited testing laboratories available? If yes, specify the test reports in list:	☐ Yes ☐ No
List of documents concerning to manufacturer's quality system (*certificates, audit reports, …*)	
Another documents (*information, …*):	

Guidance for proper filling of particular fields in the application form

Data in the first table under legend APPLICANT serve to identification of manufacturer and are on the certificate inscribed. There is strictly necessary to specify the exact name and address of the manufacturer (data shall be identical with those printed on the label of medical devices under scope of certification and VAT number or other Identification number. Information about bank requisites (*bank name, account number, SWIFT code*) is important for the sake of contract proposal and information about contact persons with e-mail, phone and fax number as well.

The second table must be duly complete with product trade names, which will be on relevant certificates uploaded, and the devices classification in relation to device intended use specified by the manufacturer (*Classification rules are laid down in Annex IX of the Directive 93/42/EEC*). Detailed specification of devices concerning type and/or model can be filled in referring to appropriate parts of page 2.

The manufacturer shall identify if the devices contain as an integral part a human blood derivates since then a specific procedure will be enforced.

Information in the further section shall be given in the event of the manufacturer's name and address is different from applicant’s one or in the case that the company is an integral part of some larger organization.

Conformity assessment procedure shall be specified in the third table considering the classification mentioned above.

The further three declarations express the applicant’s agreement with the common conditions of the conformity assessment procedure applied by TIC. Client’s signature and date of application are strongly necessary.

On the second page, the name of devices shall be inscribed in the first line together with product, its main parts and critical material description (especially when a medicine, animal tissues or blood derivatives are used in the medical device).

Within second line important parts of technical documentation with decisive impact on classification of the devices in relation to intended use and critical material shall be listed.

In the further line, the intended use of devices shall be described in detail.

Next part of the table shall provide an assessor with information whether these devices were placed on the market, when and in which countries in order that the relevant information and experiences of end-users from post-production phase of the devices should be corroborated.

Additional enquiries concern a manufacturer's quality system and its possible certification. This information is important and helpful to auditors with arrangement of an audit and quality system documents review.

Next line shall contain not only certificates but also list of documents relative to manufacturer's quality system, especially when the system hasn't been certified yet (standard operational procedures, work instructions etc.).

The last part of the table involves information concerning main subcontractors, theirs quality system, contractual liaison etc.