Application for Certification according to IVDD 98/79/EC

After being checked and signed by mdc this application is a valid

Certification Contract

between

mdc medical device certification GmbH,
Kriegerstraße 6, 70191 Stuttgart, Germany

(in the following called mdc)

and

Customer Number (filled in by mdc)

Company (Name and Legal Entity)	
Contact Person	
Street	Postal Code, Place
Country	E-Mail Address
Phone	Fax
Further site(s), branches and manufacturing plants where the quality system is applied (detailed information about name and legal entity)	

(in the following called applicant).

By order of the applicant, mdc performs a conformity assessment procedure according to IVDD 98/79/EC as specified on page 2. mdc will conduct this conformity assessment according to the applied scope.

This contract is based on our **"General Terms of Business of mdc medical device certification GmbH" (120301/9)**, the **"Process Description Certification of Quality Systems" (120303/9)**, the **"Regulations for Certification Processes" (120304/7)**, the **"Specific Regulations for Certification Processes according to MDD 93/42/EEC and IVDD 98/79/EC" (120305/3)**, the **"Price List" (120302/11)** and the **"Use of Certification, Certificate and Certification Mark" (170101/6)**.

This contract is valid starting with the signature date through the expiration of the initial certification unless otherwise agreed during the offer process or the order process. The termination of this contract has to be effected according to our terms of business.

Contractual amendments and changes have to be in writing. No additional agreements are in existence. If single definitions of this contract should eventually become ineffective, the validity of the other regulations will not be affected by this. The ineffective clause has to be substituted by an effective clause, which is comparable as close as possible to the basic meaning.

mdc medical device certification	**Application for Certification according to IVDD 98/79/EC**

Products or Product Categories

Name			
Purpose of use			
Category	☐ Annex II, List A	☐ Annex II, List B	☐ Devices for self testing
Conformity assessment procedure	☐ Annex IV	☐ Annex VII	☐ Annex III.6

Name			
Purpose of use			
Category	☐ Annex II, List A	☐ Annex II, List B	☐ Devices for self testing
Conformity assessment procedure	☐ Annex IV	☐ Annex VII	☐ Annex III.6

Name			
Purpose of use			
Category	☐ Annex II, List A	☐ Annex II, List B	☐ Devices for self testing
Conformity assessment procedure	☐ Annex IV	☐ Annex VII	☐ Annex III.6

Details about the medical devices can also be stated on a separate list. This list has to contain all details mentioned above, including page numbers and binding signature.

With the application the applicant declares:

- that he did not submit to any other Notified Body a similar application for the same quality management system referring to the named products,
- to fulfill the duties, which occur from the approved QM-system and to maintain it, that the suitability and effectiveness is guaranteed,
- to set up a systematic procedure, where the experiences with products in the phases subordinated to the production can be analyzed, to hold it up-to-date and to take precautions to perform necessary corrections. In addition he declares to inform the competent authority immediately about the following incidents:
  - I. every dysfunction or every change of the characteristic and/or performance as well as every improper use of the labeling or the instructions of the product, which causes or caused the death or a considerable weakening of the patient's or user's condition,
  - II. every technical or medical reason, which is up to the characteristic and performance of the product named under I) and causes a systematical recall of all products of the same type by the manufacturer.
- to make all relevant information available.

We hereby declare that we have received, accept and fulfill the obligations of the documents mentioned on page 1 during the terms of contract.

We apply for the certification according to the above chosen standards.

Date, Stamp

The contract is valid from: _________________

mdc medical device certification GmbH
Kriegerstraße 6, 70191 Stuttgart, Germany

____
(Binding Signature Applicant)

____
(Name in Block Capitals)

____
(Binding Signature mdc)

____
(Name in Block Capitals)