mdc	**Application for Certification according to QM Standards**	028/03.2024 ID: 414

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

with the location of the conformity assessment body at
Ernst-Augustin-Straße 2, 12489 Berlin, Germany

(in the following called mdc)

and

Customer Number (filled in by mdc)
«Kundennummer»

Company (Name and Legal Entity) «Firmenname»	
Contact Person «Ansprechperson»	
Street «Strasse»	Postal Code, Place «Ort»
Country «Land»	E-Mail Address «Email»
Phone «Fon»	Fax «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 the quality standards chosen on page 2. mdc will conduct this conformity assessment according to the applied scope.

This contract is based on our **"General Terms of Business"** (396/015), the **"Process Description Certification of Quality Systems"** (400/013), the **"General Rules for Certification Procedures"** (402/013), the **"«PreislisteEN»"** («PreislisteNummerEN») and the **"Use of Certification, Certificate and Certification Mark"** (562/011).

This contract is valid starting with the signature date through the expiration of the certification unless otherwise agreed during the offer process or the order process. The termination of this contract has to be effected according mdc's 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 become ineffective, the validity of the other provision 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 original meaning.

mdc	**Application for Certification according to QM Standards**	028/03.2024 ID: 414

Applied for certification according to offer

☐ **EN ISO 13485:2016**

☐ with additional acceptance in **Taiwan**
mdc prticipates in the Technical Cooperation Programme[1]

☐ **EN ISO 9001:2015**

Subject and scope of certification

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

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

Date, Stamp

mdc medical device certification GmbH

(Binding signature applicant*)

(Date, signature mdc)

(Name in block capitals)

(Name in block capitals)

* Person listed in the commercial registration / national company register or authorised by the power of attorney available on our website.

[1] "Technical Cooperation Programme on Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports between EU MDR/IVDR Notified Body Partners and R.O.C. TFDA Authorized Medical Device QMS Auditing Organizations"