Certificate

mdc medical device certification GmbH

certifies that

ENDOSMART® Gesellschaft für Medizintechnik mbH Wilhelm-Schickard-Straße 9c 76131 Karlsruhe Germany

with the locations listed in the attachment

for the scope

development and production of medical devices made of shape memory alloys as well as surgical instruments made of titanium and metal alloys, a combination of titanium and metal alloys and shape memory alloys in cleanroom environment

production of implants on behalf of customer specifications in clean room environment

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from Valid until Registration no. Report no. Stuttgart 2023-08-08 2025-03-15 D1084600016 P23-00600-266590 2023-08-08

Head of Certification Body





Internet: http://www.mdc-ce.de

Attachment of the certificate

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Location	Scope
ENDOSMART® Gesellschaft für Medizintechnik mbH Wilhelm-Schickard-Straße 9c 76131 Karlsruhe	development and production of medical devices made of shape memory alloys as well as surgical instruments made of titanium and metal alloys, a combination of titanium and metal alloys and shape memory alloys in cleanroom environment production of implants on behalf of customer specifications in clean room environment
ENDOSMART® Gesellschaft für Medizintechnik mbH Lorenzstraße 6 76297 Stutensee	



Head of Certification Body