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:2016 - ISO 13485:2016

Valid from	2022-03-16
Valid until	2025-03-15
Registration no.	D1084600015
Report no.	P22-00036-225375
Stuttgart	2022-02-24

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
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Attachment of the certificate

No. D1084600015 date 2022-02-24

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	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

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