EU Quality Management System Certificate

We hereby certify the company

H. + H. Maslanka Chirurgische Instrumente GmbH
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78532 Tuttlingen
Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2024-02-27	Registration No.	D1038400078
Valid until	2027-08-17	Report No.	P21-01922-290155

Stuttgart, 2024-02-27

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Transseptal needle and transseptal catheter

Risk class: III

Flex-Pusher I and II

Risk class: III

Unitip-Applicator

Risk class: IIa

Cardio-biopsy forceps and cardio grasping forceps

Risk class: III

Notes:

For the placing on the market of class III and IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors within the meaning of Regulation (EU) 2017/745, Art. 52 (4), 2nd paragraph and with the exception of custom-made devices of class III), an EU technical documentation assessment certificate is also required.

The certificate is based on the previous certificate

D1038400076 dated 2023-11-20 with the following changes:
Supplemented by cardio-biopsy forceps and cardio grasping forceps