EU Technical Documentation Assessment Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000005600)

H. + H. Maslanka Chirurgische Instrumente GmbH

Stockacher Straße 172
78532 Tuttlingen
Germany

has submitted a technical documentation for the devices listed on the following pages in accordance with Annexes II and III of Regulation (EU) 2017/745, which fulfils the following requirements:

Annex IX - Chapter II (Assessment of the Technical Documentation)

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

The certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-11-20	Registration No.	D1038400077
Valid until:	2028-05-07	Evaluation Report No.	P22-01375-246092

Stuttgart, 2023-11-20

Head of Notified Body

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

Devices:

Product:
Transseptal needle with transseptal catheter

Intended purpose:
The transseptal needle is used only in combination with a transseptal catheter (safety sheath) for the crossing of the interatrial septum in order to perform transseptal left atrial or left ventricular procedures.

Risk class: III
Basic-UDI-DI: 42 511211 TD06 BK

Notes:

For the placing on the market of the devices an EU Quality Management System Certificate according to Annex IX, Chapter I of Regulation (EU) 2017/745 on medical devices is also required.

The certificate is based on the previous certificate D1038400074 dated 08.05.2023 with the following changes:
The product „Transseptal needle“ was supplemented by „transseptal catheter“.

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