EU Quality Management System Certificate

mdc medical device certification GmbH

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

hereby certifies that the company

Albert Heiss GmbH & Co. KG

Stockacher Straße 138
78532 Tuttlingen
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

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

Annex IX - Chapter I (Quality Management System)

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 consists of 4 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2021-11-29	Registration No.	D1342300004
Valid until:	2026-11-28	Evaluation Report No.	202957

Stuttgart, 2021-11-29

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

Head of Notified Body

Devices:

Product: Hook

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010002WM

Product: Loop

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010014WU

Product: Spatula

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010016WY

Product: Retractor

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010023WV

Product: Cannula, eye

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010004WR

Product: Needle holder

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010010WL

Product: Forceps

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010012WQ

Product: Clamp

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010005WT

Product: Spoon

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010006WV

Product: Spud

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010008WZ

Product: Knife

Risk class: I (reusable)
Basic-UDI-DI: 4250326800010009X3

Product: Scissors

Risk class: I (reusable)

Basic-UDI-DI: 4250326800010013WS

Product: Trephine

Risk class: I (reusable)

Basic-UDI-DI: 4250326800010021WR

Product: Punches

Risk class: I (reusable)

Basic-UDI-DI: 4250326800010017X2

Product: Glaucoma punch

Risk class: I (reusable)

Basic-UDI-DI: 4250326800010001WK

Notes:

In the case of class I devices that are reusable surgical instruments the involvement of mdc is limited to the assessment of the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing as well as the related instructions for use.