EU Quality Assurance Certificate

mdc medical device certification GmbH

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

hereby certifies that the company (SRN: DE-MF-000005842)

C. Bruno Bayha GmbH

Dr. Karl-Storz-Straße 14
78532 Tuttlingen
Germany

has implemented and applies a quality management system in accordance with Annex XI, Part A, Section 6 of Regulation (EU) 2017/745 for manufacturing and final inspection of the devices listed on the following pages.

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

Annex XI - Part A (Production Quality Assurance)

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 XI, Section 7 of Regulation (EU) 2017/745.

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:	2023-06-12	Registration No.	D1495700002
Valid until:	2028-05-23	Evaluation Report No.	P21-01380-213705

Stuttgart, 2023-06-12

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: sterile BAYHA-scalpel blades

Risk class: IIa

Product: BAYHA-scalpel handles, reprocessable

Risk class: I (reusable)

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.