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

Frimed Medizintechnik GmbH

Junkersstraße 1
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)

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 consists of 6 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2022-03-21	Registration No.	D1034300030
Valid until:	2027-03-20	Evaluation Report No.	213330

Stuttgart, 2022-03-21

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: Drill Instruments

Risk class: I (reusable)

Product: Awls

Risk class: I (reusable)

Product: Trephines

Risk class: I (reusable)

Product: Tracheal Dilators

Risk class: I (reusable)

Product: Vascular Dilators

Risk class: I (reusable)

Product: Biliary Dilators

Risk class: I (reusable)

Product: Dermatomes

Risk class: I (reusable)

Product: Hammers

Risk class: I (reusable)

Product: Elevators

Risk class: I (reusable)

Product: Probes

Risk class: I (reusable)

Product: Spatulas

Risk class: I (reusable)

Product: Bulldog Clamps

Risk class: I (reusable)

Product: Clamps

Risk class: I (reusable)

Product: Chisels

Risk class: I (reusable)

Product: Osteotomes

Risk class: I (reusable)

Product: Knifes

Risk class: I (reusable)

Product: Meniscus Knife

Risk class: I (reusable)

Product: Knife Handles

Risk class: I (reusable)

Product: Suture Guides

Risk class: I (reusable)

Product: Needles

Risk class: I (reusable)

Product: Needle Holders

Risk class: I (reusable)

Product: Tweezers

Risk class: I (reusable)

Product: Bone Files

Risk class: I (reusable)

Product: Curettes, Bone Curettes

Risk class: I (reusable)

Product: Bone Rasp

Risk class: I (reusable)

Product: Saws

Risk class: I (reusable)

Product: Scissors

Risk class: I (reusable)

Product: Snare Instruments

Risk class: I (reusable)

Product: Tonsil Lacerators

Risk class: I (reusable)

Product: Punches

Risk class: I (reusable)

Product: Bone Punches

Risk class: I (reusable)

Product: Strippers

Risk class: I (reusable)

Product: Tracheal Hooks

Risk class: I (reusable)

Product: Forceps

Risk class: I (reusable)

Product: Gouge Forceps

Risk class: I (reusable)

Product: Biopsy Forceps

Risk class: I (reusable)

Product: Obstetric Forceps

Risk class: I (reusable)

Product: Bone Forceps

Risk class: I (reusable)

Product: Retractors

Risk class: I (reusable)

Product: Tonsil Forceps

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.