

# EU Quality Management System Certificate

We hereby certify the company

**Frimed Medizintechnik GmbH**  
**Junkersstraße 1**  
**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 6 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2026-02-25  
Valid until 2027-03-20

Registration No. D1034300036  
Report No. P25-00482-330677

Stuttgart, 2026-02-25



Notified Body



## Devices:

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Drill Instruments

Risk class: I (reusable)

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Awls

Risk class: I (reusable)

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Trephines

Risk class: I (reusable)

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Tracheal Dilators

Risk class: I (reusable)

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Vascular Dilators

Risk class: I (reusable)

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Biliary Dilators

Risk class: I (reusable)

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Dermatomes

Risk class: I (reusable)

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Hammers

Risk class: I (reusable)

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Elevators

Risk class: I (reusable)

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Probes

Risk class: I (reusable)

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Spatulas

Risk class: I (reusable)

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Bulldog Clamps

Risk class: I (reusable)

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Clamps

Risk class: I (reusable)

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Chisels

Risk class: I (reusable)

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Osteotomes

Risk class: I (reusable)

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Knives

Risk class: I (reusable)

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Meniscus Knife

Risk class: I (reusable)

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Knife Handles

Risk class: I (reusable)

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Suture Guides

Risk class: I (reusable)

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Needles

Risk class: I (reusable)

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Needle Holders

Risk class: I (reusable)

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Tweezers

Risk class: I (reusable)

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Bone Files

Risk class: I (reusable)

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Curettes, Bone Curettes

Risk class: I (reusable)

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Bone Rasp

Risk class: I (reusable)

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Saws

Risk class: I (reusable)

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Scissors

Risk class: I (reusable)

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Snare Instruments

Risk class: I (reusable)

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Tonsil Lacerators

Risk class: I (reusable)

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Punches

Risk class: I (reusable)

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Bone Punches

Risk class: I (reusable)

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Strippers

Risk class: I (reusable)

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Tracheal Hooks

Risk class: I (reusable)

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Retractors

Risk class: I (reusable)

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Gouge Forceps

Risk class: I (reusable)

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Biopsy Forceps

Risk class: I (reusable)

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Obstetric Forceps

Risk class: I (reusable)

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Bone Forceps

Risk class: I (reusable)

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Forceps

Risk class: I (reusable)

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Tonsil Forceps

Risk class: I (reusable)

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Self-Retaining Retractors, Wound Hooks

Risk class: IIa

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Suction Instruments

Risk class: IIa

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## Notes:

In the case of class I devices that are reusable surgical instruments the involvement of mdc is limited to 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.

## The certificate is based on the previous certificate

D1034300030 (2022-03-21)

with the following changes to D1034300030:

Product groups Suction Instruments and Self-Retaining Retractors, Wound Hooks added