

EU Quality Management System Certificate

We hereby certify the company

Dufner Instrumente GmbH
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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 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2026-06-19
Valid until 2030-10-16

Registration No. D1524100003
Report No. P26-00528-365007

Stuttgart, 2026-06-19



Notified Body



Devices:

Endoscopic monopolar and bipolar HF electrodes

Intended purpose: Electrodes are used to cut and coagulate soft tissue during surgical procedures. A key advantage over conventional scalpel-based cutting techniques is that the use of high-frequency current allows bleeding to be stopped simultaneously by sealing the affected blood vessels.

Risk class: IIb

HF electrodes for open surgery

Intended purpose: The HF electrode is used for the targeted transmission of HF current from the HF generator via the lead cable to the patient. The electrode insulation also serves to isolate the current-carrying electrode core from the patient and the user, in order to prevent unintended coagulation or burns at locations other than the electrode tip. Electrodes are used to cut through, dissect and simultaneously coagulate tissue structures and blood vessels. With HF instruments, it is possible to coagulate immediately at any desired location in a highly precise manner tailored to the situation, i.e. haemostasis is achieved.

Risk class: IIb

HF biopsy forceps

Intended purpose: HF biopsy forceps are used to take tissue samples. With HF instruments, it is possible to coagulate immediately at any point, in a highly precise manner tailored to the situation; in other words, haemostasis is achieved.

Risk class: IIb

Monopolar and bipolar HF scissors

Intended purpose: HF scissors are used to separate tissue, whether by spreading it apart, sweeping it aside or cutting directly through it. The simultaneous application of HF current enables very rapid, time-saving and low-bleeding surgery. In high-frequency surgery (also known as diathermy or electrocautery), high-frequency alternating current is passed through the human body to selectively damage or cut tissue. A key advantage over conventional scalpel techniques is that haemostasis can be achieved simultaneously with the incision by sealing the affected vessels. Scissors come in various shapes and sizes. Curved scissors that can be rotated have the advantage that the tip can be seen whilst cutting.

Risk class: IIb

Monopolar and bipolar HF dressing forceps

Intended purpose: In surgery, forceps are used for diagnostic purposes, to palpate the dimensions, position and firmness of tissue, to scrape tissue structures, and for blunt, atraumatic dissection. Haemostasis is achieved through coagulation using high-frequency current.

Risk class: IIb

Monopolar and bipolar HF clamps

Intended purpose: Clamps are instruments used in endoscopic surgery to clamp tissue and, where necessary, to coagulate it. The handles are usually fitted with a safety mechanism (lock) that prevents the clamps from opening accidentally during the procedure.

Risk class: IIb

Cutting and tissue-removing reusable surgical instruments including cutting and tissue-removing reusable surgical instruments for ophthalmology

Risk class: I (reusable)

Holding and grasping reusable surgical instruments including holding and grasping reusable surgical instruments for ophthalmology

Risk class: I (reusable)

Dilating and retracting reusable surgical instruments including dilating and retracting reusable surgical instruments for ophthalmology

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 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.