

EU Quality Management System Certificate

We hereby certify the company

Getsch + Hiller Medizintechnik GmbH
Sattlerstraße 20
78532 Tuttlingen-Nendingen
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 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2026-05-08
Valid until 2029-10-24

Registration No. D1170000004
Report No. P23-01000-357070

Stuttgart, 2026-05-08



Notified Body



Devices:

Grasping forceps and scissors, including corresponding shafts and PEEK handles, for laparoscopy with HF connection

Intended purpose: The dismountable laparoscopic instruments with HF connection from Getsch+Hiller Medizintechnik GmbH are intended for use with monopolar HF current.

Depending on the work application, the microsurgical laparoscopy grasping forceps (MIS instruments) with HF connection are used for grasping, dissecting tissue, organs and vessels. Laparoscopic scissors with HF connection are used for cutting tissue, organs and vessels. When using HF current, the instruments are used to dissect and simultaneously coagulate tissue and vessels.

Risk class: IIb
