

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 (SRN: DE-MF-000005910)

REGER Medizintechnik GmbH

Gewerbestraße 10
78667 Villingendorf
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 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:	2022-12-14	Registration No.	D1228500016
Valid until:	2027-12-13	Evaluation Report No.	226846

Stuttgart, 2022-12-14



Head of Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zfg.de
BS-MDR-098

Devices:

Product: Shaver non-sterile

Risk class: IIa

Product: Shaver sterile

Risk class: IIa

Product: Bur non-sterile

Risk class: IIa

Product: Bur sterile

Risk class: IIa

Statement on GREEN Requirements

REGER Medizintechnik GmbH, Gewerbestraße 10, 79667 Villingendorf, Germany, manufacturer of medical devices and accessories, hereby states that our manufacturing process for the Shavers and Burs, meets the following principle of the GREEN REQUIREMENTS, according to the Order No. D1-508 of the Minister of Environmental Protection of the Republic of Lithuania on 28-06-2011 (wording of Order No. DI-401 on 13-12-2022) 4.4.4, in one, several or all stages of the product's life cycle

3) 4.4.4.3 p. less or no dangerous chemicals, toxins and other harmful substances from the point of view of environmental protection are used to produce the product and/or packaging, the environment is not polluted.

Villingendorf, 21. September 2023.



ppa. Christoph Schumacher
Commercial Director
REGER Medizintechnik GmbH