For electronic distribution only
Nur zur elektronischen Verbreitung

EU Quality Management System Certificate

We hereby certify the company

PMS Präzisions Medizinische Spezialitäten GmbH
Kreuzstraße 5
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 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2026-03-09	Registration No.	D1470100006
Valid until	2030-02-27	Report No.	P24-00923-304026

Stuttgart, 2026-03-09

Notified Body

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

Devices:

Reusable ophthalmic surgical instruments for manipulating, grasping, and spreading; irrigation and aspiration; cutting, scraping, splitting, and separating

Risk class: I (reusable)

Reusable ophthalmic surgical instruments with a measuring function for cutting, scraping, splitting, and separating

Risk class: I (reusable, measuring function)

Notes:

For class I devices with a measuring function the involvement of mdc is limited to the aspects relating to the conformity of the devices with the metrological requirements.

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.