

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-000013293)

OPTOSOL Chemische Produkte GmbH

Oskar-von-Miller-Straße 6
83714 Miesbach
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:	2023-02-14	Registration No.	D1016800007
Valid until:	2028-02-13	Evaluation Report No.	P22-00916-238778

Stuttgart, 2023-02-14



Head of Notified Body



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

Devices:

Product:

Care products for contact lenses [i-clean, CL 55, CL 22, OptoCare Plus, OptoCare Sensitiv, CL-KS]

Intended purpose:

Cleaning, disinfection, neutralization, storage solution for soft hydrophilic contact lenses, rigid contact lenses RGP; rinsing solution for all types of contact lenses

Risk class: IIb

Product:

Nasal spray Hyaluron

Risk class: IIa
