

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III Certificate No. MDR-0020

Issued to: PHARMA PRODUCT DOO,

Koste Glavinića 2, 11000 Beograd, Serbia

SRN of the manufacturer: RS-MF-000024163

EU authorised representative: TNMC Devices (Llc)
Ulica Franje Krežme 1, 10000 Zagreb, Croatia

SRN of EU authorised

representative: HR-AR-000019582

SIQ has audited the quality management system in accordance with MDR Annex IX and found that the above-mentioned Manufacturer's quality management system meets the requirements of the Regulation (EU) 2017/745 concerning medical devices Annex IX. Devices covered by the Manufacturer's quality management system are listed on the page(s) below.

This certificate is based on

Audit reports No.:

OSV 01340/2023, 2023-10-27,

OSV 01684/2023, 2023-12-29,

OSV 00067/2024, 2024-01-31,

OSV 00722A/2024, 2024-05-27,

OSV 01234/2024, 2024-09-27,

OSV 01177/2024, 2024-09-25,

OSV 01235/2024, 2024-09-27,

OSV 01338/2024, 2024-09-30.

See also decision of NB's commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality management system is subject to periodical surveillance as referred to in Regulation (EU) 2017/745 concerning medical devices Annex IX and continues to meet the above requirements.

Reference to any previous certificate: MDR-0020/01

Certification date: 2024-10-24

Issue: 02/2025-05-23

Valid until: 2029-10-23

Managing Director of SIQ

Gregor Schoss

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EU Quality Management System Certificate Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III Certificate No. MDR-0020

Device: CONTACT LENSES STORING AND CLEANING SOLUTIONS

EMDN: Q02030204

Intended purpose: LENS CARE is intended for cleaning, removing deposits of

proteins and lipids, disinfecting, wetting, and storing all kinds of soft contact lenses. It is intended for use of soft lens wearers (adults and children), strictly indicated by lens care professionals (ophthalmologists) for the purpose of correcting visual acuity. The eye structures which are in close contact with

the LENS CARE solution are the conjunctiva and cornea.

Classification:

Specific conditions for or

provisions or

limitations to the validity of certificate: /

Certification date:

2024-10-24

Issue:

02/2025-05-23

Valid until:

2029-10-23

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