



Declaration of Conformity

Manufacturer: TRB CHEMEDICA AG
Address: Otto-Lilienthal-Ring 26, D - 85622 Feldkirchen
Product: REMOGEN OMEGA
Intended use: Lubricant eye drops
Classification: Class IIa according to MDD, Annex IX, rule 5
Conformity assessment route: MDD, Annex II.3

We herewith declare under our sole responsibility that the above mentioned product complies with the requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices (MDD). All supporting documentation is retained under the premises of the manufacturer.

Standards applied: For the harmonized standards applicable to this product please refer to the effective manufacturer's List of Norms and Standards
Notified Body: TÜV Süd Product Service GmbH (0123)
Ridlerstraße 65, D - 80339 München
EC Certificate: G1 027625 0070 Rev. 01, Annex II.3, MDD 93/42/EEC
Valid until: 26.05.2024
Date, when CE mark was affixed: 18.07.2011 (NB ISS Rome)
Transfer to NB TPS: 14.08.2015
Launch Date: 19.07.2011

Place, Date: Feldkirchen, 27.07.2023

Signature:
Name:
Position:

A handwritten signature in blue ink that reads 'Carola Trümper'.

- Carola Trümper -
Director RA/QA, PRRC

TRB CHEMEDICA AG

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Aufsichtsrat: Jens Horstkotte / Vorstand: Hans Kalkbrenner, Isaac Abad / HRB München: 114049 / USt-IdNr.: DE 182195789