



## 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 excluding (4)

**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 excluding (4),  
MDD 93/42/EEC

Valid until: 26.05.2024

Based on Regulation (EU)  
2023/607, the EC certificate shall  
be continued to be valid until: 31.12.2028

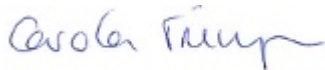
Date, when CE mark was affixed: 19.07.2011 (NB ISS Rome)

Transfer to NB TPS: 14.08.2015

Launch Date: 19.07.2011

Place, Date: Feldkirchen, 17.06.2024

Signature:  
Name:  
Position:

  
\_\_\_\_\_  
- Carola Trümper -  
PRRC

### TRB CHEMEDICA AG

Otto-Lilienthal-Ring 26 / 85622 Feldkirchen b. München, Deutschland  
Tel +49 (0)89 46 14 83-0 / Fax +49 (0)89 46 14 83-85 / [info@trbchemedica.de](mailto:info@trbchemedica.de) / [www.trbchemedica.de](http://www.trbchemedica.de)  
Aufsichtsrat: Jens Horstkotte / Vorstand: Hans Kalkbrenner, Isaac Abad / HRB München: 114049 / USt-IdNr.: DE 182195789