



Declaration of Conformity

Manufacturer: TRB CHEMEDICA AG
Address: Otto-Lilienthal-Ring 26, D - 85622 Feldkirchen
Product: VISIOL
Intended use: Viscoelastic solution for ocular surgery
Classification: Class IIb according to MDD, Annex IX, rule 8
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: 14.11.2001
Launch Date: 01.05.2002
Place, Date: Feldkirchen, 08.04.2026

Signature:
Name:
Position:

- Carola Trümper -
PRRC

TRB CHEMEDICA AG

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