




## 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, 23.05.2024

Signature:  
Name:  
Position:

  
- Hans Kalkbrenner -  
Management Representative

### TRB CHEMEDICA AG

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