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: - C a r o l a T r ü m p e r -

Position: PRRC

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