Declaration of Conformity

Manufacturer:	TRB CHEMEDICA AG
Address:	Otto-Lilienthal-Ring 26, D - 85622 Feldkirchen
Product:	VISCOSEAL SYRINGE ARTROJECT
Intended use:	Synovial fluid substitute
Classification:	Class III according to MDD, Annex IX, rule 7 sentence 4
Conformity assessment route:	MDD, Annex II excluding (4) and Annex II.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
EC Certificate:	G7 0 27625 076 Rev.01, Annex II.4, MDD 93/42/EEC
Valid until:	26.05.2024
Based on Regulation (EU) 2023/607, the EC certificates shall be continued to be valid until:	31.12.2027
Date, when CE mark was affixed:	18.11.2011
Launch Date:	22.11.2011

Place, Date: Feldkirchen, 24.10.2024

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