



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:

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