



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.3 and II.4
Manufacturing site: Pharmpur GmbH, Messerschmittring 33,
D - 86343 Königsbrunn

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.3, 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: May 26th, 2024
Date, when CE mark was affixed: 20.11.2011
Launch Date: 21.11.2011
Place, Date: Feldkirchen, 28.07.2023

Signature:
Name:
Position:

- Carola Trümper -
Director RA/QA

TRB CHEMEDICA AG

Otto-Lilienthal-Ring 26 / 85622 Feldkirchen b. München, Deutschland
Tel +49 (0)89 46 14 83-0 / Fax +49 (0)89 46 14 83-85 / info@trbchemedica.de / www.trbchemedica.de
Aufsichtsrat: Jens Horstkotte / Vorstand: Hans Kalkbrenner, Isaac Abad / HRB München: 114049 / USt-IdNr.: DE 182195789