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: Valid until:	G1 027625 0070 Rev. 01, Annex II.3, MDD 93/42/EEC 26.05.2024
EC Certificate: Valid until:	G7 0 27625 076 Rev.01, Annex II.4, MDD 93/42/EEC 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: - Carola Trümper -

Position: 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