IVF HARTMANN AG
Victor-von-Bruns-Strasse 28
Postfach 634
CH-8212 Neuhausen

Phone: +41 52 674 31 11
Fax: +41 52 672 74 41
info@ivf.hartmann.info
ivf.hartmann.info

HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity Class I

Neuhausen, 2023-AUG-18

We herewith declare under our sole responsibility that the Class I medical devices listed below, first placed on the market by IVF HARTMANN AG, satisfy the applicable provisions, in particular the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (7) have been performed and the Technical Documentation is kept available.

EC-REP: PAUL HARTMANN AG, Paul-Hartmann-Straße 12, 89522 Heidenheim, Germany

Single Registration Number of Authorized Representative: DE-AR-000007519

Single Registration Number of Manufacturer: CH-MF-000015962

Swiss Single Registration Number of Manufacturer: CHRN-MF-20000305

High Level Intended Purpose	Non-active, non-implantable devices for wound and skin care		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
DermaPlast Compress Protect (scope see Table 1)	3296	Rule 4, indent 1	76116003296N5

IVF HARTMANN AG

i.V.

Andrea Marti
Regulatory Affairs Manager

i.V.

Susanne Frei
Teamleader Regulatory Affairs

Valid until: 2028-JUN-13

Table 1: Scope

REF	Description
550201	DermaPlast Compress Protect unst. 5x7,5cm
550211	DermaPlast Compress Protect unst. 7,5x10cm