

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 Gel, M-Plast Gel Pads, Conviva Gelkompressen non-sterile (scope see Table 1)	1422	Rule 4, indent 1	76116001422M4

IVF HARTMANN AG

i.V.



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Valid until: 2028-JUN-13

Table 1: Scope

REF	Description
218700	DermaPlast Compress Gel 5x5cm
218710	DermaPlast Compress Gel 5x7,5cm
218720	DermaPlast Compress Gel 7,5x10cm
297020	M-Plast Gel Pads 5x7,5cm
528050	Conviva Gelkompress 10x7,5cm