

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 Plus non-sterile (scope see Table 1)	3295	Rule 4, indent 1	76116003295N3

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
550301	DermaPlast Compress Plus unst. 5x7,5cm
550311	DermaPlast Compress Plus unst. 7,5x10cm
550321	DermaPlast Compress Plus unst. 7,5x20cm