

## 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.



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Valid until: 2028-JUN-13

Table 1: Scope

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