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EU-Declaration of Conformity

Neuhausen, 30th October 2020

We herewith declare,

Object of declaration: DermaPlast Compress Protect (3296) (scope see Table 1)

which was first placed on the market by IVF HARTMANN AG, meets 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 Procedure according to Article 52(7) has been performed and the Technical Documentation is kept available.

This EU-Declaration of Conformity is issued under the sole responsibility of the IVF HARTMANN AG.

The product has been identified as a medical device in risk class I according to Rule 4 indent 1 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 76116003296N5

Single Registration Number: not yet available

IVF HARTMANN AG:

i.V. David Wolf
Regulatory Affairs Manager

Translation available at / Übersetzung verfügbar unter / Traduction disponible à / Traduzione disponibile su: http://www.ivf.hartmann.info/certificate

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Table 1: Scope

REF	Description
550201	DermaPlast Compress Protect unst. 5x7,5cm P10 West
550211	DermaPlast Compress Protect unst. 7,5x10cm P15 West