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EU-Declaration of Conformity

Neuhausen, 21st December 2020

We herewith declare,

Object of declaration: DermaPlast Compress Gel, M-Plast Gel Pads, Conviva Gelkompresse non-sterile (1422) (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: 76116001422M4

Single Registration Number: not yet available

IVF HARTMANN AG:

i.V. Susanne Frei
Regulatory Affairs Senior 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
218700	DermaPlast Compress Gel 5x5cm P20 K189
218710	DermaPlast Compress Gel 5x7,5cm P20 K147
218720	DermaPlast Compress Gel 7,5x10cm P10 K147
297020	M-Plast Gel Pads 5x7,5cm P20 K10 Migros
528050	Conviva Gelkompresse 10x7,5cm P10