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EU-Declaration of Conformity

Neuhausen, 28th May 2020

We herewith declare,

Object of declaration: Compresses non-sterile (1188, 1402, 3506) (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: see Table 1

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	Product code	Basic UDI-DI	Description
210060	1188	76116001188MK	Gazekompressen ust 24fd 20x20cm P500
984030	1402	76116001402LW	ASM Gazekompr. KVB 8x12cm P80
214010	1402	76116001402LW	DermaPlast Komp 4x6cm 24fd P80
214020	1402	76116001402LW	DermaPlast Komp 6x8cm 24fd P80
214030	1402	76116001402LW	DermaPlast Komp 8x12cm 24fd P80
214040	1402	76116001402LW	DermaPlast Komp 10x10cm 24fd P80
831010	3506	76116003506MR	ES-Kompressen ust Wa 5x5 8f17fd P100
831020	3506	76116003506MR	ES-Kompressen ustWa 7,5x10 8f17fd P100
831030	3506	76116003506MR	ES-Kompr ust Wa 10x10 8f 17fd P100
831040	3506	76116003506MR	Longuetten ust Wa 10x20 4f 17fd P100