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EU-Declaration of Conformity

Neuhausen, 08th October 2020

We herewith declare,

Object of declaration: DermaPlast Sparablanc (1498, 1499) (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 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. 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	Product code	Basic UDI-DI	Description
521011	1498	76116001498N5	DP Sparab Textil 1,25cmx5m P1
521021	1498	76116001498N5	DP Sparab Textil 2,5cmx5m P1
521311	1499	76116001499N7	DermaPl Sparab Transp 1,25cmx5m
521321	1499	76116001499N7	DP Sparab Transp 2,5cmx5m P1
521330	1499	76116001499N7	DermaPl Sparab transp 1,25cmx9,2m
521340	1499	76116001499N7	DermaPl Sparab transp 2,5cmx9,2m