IVF HARTMANN AG
Victor-von-Bruns-Strasse 28
Postfach 634
CH-8212 Neuhausen

+41 52 674 31 11
+41 52 672 74 41
info@ivf.hartmann.info
ivf.hartmann.info

EU-Declaration of Conformity

Neuhausen, 30th April 2020

We herewith declare,

Object of declaration: DermaPlast Combifix (1509) (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: 76116001509MH

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
831140	DermaPl Combifix Fingervb 50cmx4cm
831150	DermaPlast Combifix Körpervb 8cmx4m