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HARTMANN

EU-Declaration of Conformity

Neuhausen, 23rd April 2020

We herewith declare,

Object of declaration: Cooling Bandages (1083) (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: 76116001083M4

Single Registration Number: not yet available

European Representative: (REF 522013 and 522113): PAUL HARTMANN AG, Paul-Hartmann-Strasse 12, 89522 Heidenheim, Germany

IVF HARTMANN AG:

i.V. Susanne Frei
Regulatory Affairs Senior Manager

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http://www.ivf.hartmann.info/certificate

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Table 1: Scope

REF	Description
522013	DermaPlast Active Coolfix
522113	DermaPlast Active Coolfix ES PT
588813	Perskindol Cool Bandage