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HARTMANN
Helps. Cares. Protects.

EU-Declaration of Conformity

Neuhausen, 15th December 2022

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.

Device-Group: General non-active non-implantable devices used in health care and other non-active non-implantable devices

Basic UDI-DI: 76116001083M4

EU Single Registration Number: CH-MF-000015962

CH Single Registration Number: CHRN-MF-20000305

European Representative: PAUL HARTMANN AG, Paul-Hartmann-Strasse 12, 89522 Heidenheim, Germany

EU-REP Single Registration Number: DE-AR-000007519

IVF HARTMANN AG:

i.V. Susanne Frei
Teamleader Regulatory Affairs

This document is valid until: 2025-04-22

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Table 1: Scope

REF	Description
522013	DermaPlast Active Coolfix