

## EU Declaration of Conformity

Neuhausen, 2025-04-29

<b>Product Group Number</b>	1083 Cooling Bandages (scope see table 1)
<b>Manufacturer</b>	IVF HARTMANN AG Victor-von-Bruns-Strasse 28 8212 Neuhausen, Switzerland
<b>Authorized Representative</b> (only for REF 522013)	PAUL HARTMANN AG Paul-Hartmann-Straße 12 89520 Heidenheim, Germany

We herewith declare under our sole responsibility that the product listed above, first placed on the market by IVF HARTMANN AG, satisfy the applicable provisions of the following listed legislation. The conformity assessment procedures have been performed and the Technical Documentation is kept available.

### Applied legislative act

#### Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	Non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class I	Rule 1
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n.a.	
Single Registration Number	Manufacturer: CH-MF-000015962 Authorized Representative: DE-AR-000007519	
Swiss Single Registration Number	Manufacturer: CHRN-MF-20000305	
Basic UDI-DI	76116001083M4	
EMDN	Code	Term
	M03040299	Elastic Support Bandage - others
GMDN	61595	Moist-cold pressure bandage
UMDNS	15-557	Binde

IVF HARTMANN AG

i.V.



**Andrea Marti**  
Senior Regulatory Affairs Manager

i.V.



**Susanne Frei**  
Senior Regulatory Affairs Manager

Valid until: 2030-04-28

Table 1: List of products falling under the respective Product Group Number:

REF IVF	REF Migros	Description
522 013	n.a.	DermaPlast ACTIVE Coolfix
589 005	5203.606	M-Plast kühlende Bandage