

EU Declaration of Conformity

Neuhausen, 2025-05-06

Product Group Number	2244 IVF Plaster Sheaths (scope see table 1)
Manufacturer	IVF HARTMANN AG Victor-von-Bruns-Strasse 28 8212 Neuhausen, Switzerland

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.

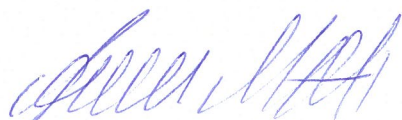
Applied legislative act

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 4, indent 1
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n.a.	
Single Registration Number	Manufacturer: CH-MF-000015962	
Swiss Single Registration Number	Manufacturer: CHRN-MF-20000305	
Basic UDI-DI	76116002244MB	
EMDN GMDN	Code	Term
	M040101	Adhesive dressings, with absorbent pad
	44990	Skin-cover adhesive strip

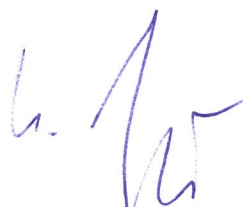
IVF HARTMANN AG

i.V.



Andrea Marti
Senior Regulatory Affairs Manager

i.V.



Dr. Heinrich Giegrich
Head of Quality & Regulatory Affairs

Valid until: 2028-OCT-29

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

REF	Description
500027	DermaPlast Pflaster-Etui Karton Rotpunkt
553230	Pflaster Etui Karton IVF
553240	Pflaster Etui Karton hf P14 ass Div Kun
553260	DermaPlast Pflasteretui Prägedruck
831500	Pflaster Etui assortiert
831510	PflasterEtui DermaPlast IVF Druck