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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Neuhausen, 2025-04-29

Product Group Number	**1509 DermaPlast Combifix** (see scope in 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	CH-MF-000015962	
Swiss Single Registration Number	CHRN-MF-20000305	
Basic UDI-DI	76116001509MH	
EMDN	Code	Term
	M040204	Absorbent dressings, wound-nonadherent
GMDN	46854	Wound-nonadherent dressing, absorbent, non-antimicrobial
UMDNS	n.a.	n.a.

IVF HARTMANN AG

i.V.

Susanne Frei
Senior Regulatory Affairs Manager

i.V.

Dr. Heinrich Giegrich
Head of RA & Quality

Valid until: 2028-JUN-13

Table 1: Scope

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