IVF HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Neuhausen, 2025-05-13

Product Group Number	3206 Alginate (scope see table 1)
Manufacturer	IVF HARTMANN AG Victor-von-Bruns-Strasse 28 8212 Neuhausen, Switzerland
Authorized Representative (only for REF 601 510)	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 4, indent 1 & Rule 5, indent 2
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	76116003206MA	
	Code	Term
EMDN	M040402	Dressings, Alginate
GMDN	58059	Plant polysaccharide haemostatic agent, non-bioabsorbable
UMDNS	15-216	Verband, sonstige

IVF HARTMANN AG

i.V.

Andrea Marti
Senior Regulatory Affairs Manager

i.V.

Susanne Frei
Senior Regulatory Affairs Manager

Valid until: 2030-06-30

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

REF IVF	REF customer	Description
601 510	N/A	DermaPlast Alginat Fl 2g
601 610	129 754	Flawa Blood Stop Alginat Fl 2g