

EU Declaration of Conformity

Neuhausen, 2025-06-03

Product Group Number	1498 DermaPlast Sparablanc Textile (scope see table 1) 1499 DermaPlast Sparablanc Transparent (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 products 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	Single-use, 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	
Swiss Single Registration Number	Manufacturer: CHRN-MF-20000305	
Basic UDI-DI	(see table 1)	
EMDN	Code	Term
	M050199	Surgical plasters - other
GMDN	16866	Basic adhesive tape

IVF HARTMANN AG

i.V.



Andrea Marti
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Dr. Heinrich Giegrich
Head of Regulatory & Quality

Valid until: 2026-DEC-31

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

REF	PGN	Basic UI-DI	Description
521011	1498	76116001498N5	DP Sparab Textil 1,25cmx5m
521021	1498	76116001498N5	DP Sparab Textil 2,5cmx5m
521311	1499	76116001499N7	DermaPI Sparab Transp 1,25cmx5m
521321	1499	76116001499N7	DP Sparab Transp 2,5cmx5m
521330	1499	76116001499N7	DermaPI Sparab transp 1,25cmx9,2m
521340	1499	76116001499N7	DermaPI Sparab transp 2,5cmx9,2m