

EU Declaration of Conformity

Neuhausen, 2025-06-03

Product Group Number	3587 Apoteket Fixation Roll (scope see table 1)
Manufacturer	IVF HARTMANN AG Victor-von-Bruns-Strasse 28 8212 Neuhausen, Switzerland
Authorized Representative	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	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 Authorized Representative: DE-AR-000007519	
Swiss Single Registration Number	Manufacturer: CHRN-MF-20000305	
Basic UDI-DI	76116003587NK	
EMDN GMDN UMDNS	Code	Term
	M050201	Extensible non-woven tapes
	16866	Basic adhesive tape
	10-028	Adhesive Strips, Hypoallergenic

IVF HARTMANN AG

i.V.



Andrea Marti
Senior Regulatory Affairs Manager

i.V.



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	Description
532000	Apoteket el.fixation 10cmx2m