

EU Declaration of Conformity

Neuhausen, 2025-12-08

Product Group Number	3207 Trauma Bandage (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	Non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class Is	Rule 4, indent 1
Conformity Assessment Procedure	Article 52 (7) and Annex XI part A with respect to sterility	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Quality Assurance Certificate (MDR) No. G26 047326 0014	
Single Registration Number	Manufacturer: CH-MF-000015962 Authorized Representative: DE-AR-000007519	
Swiss Single Registration Number	Manufacturer: CHRN-MF-20000305	
Basic UDI-DI	76116003207MC	
EMDN	Code	Term
	M030401	Elastic Compression Bandages
	GMDN	47011
UMDNS	15-216	First aid absorbent pad/bandage
		Verband, sonstige

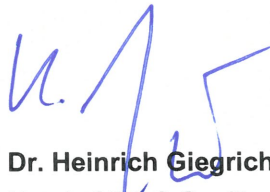
IVF HARTMANN AG

i.V.



Robert Hämmerl
Regulatory Affairs Manager

i.V.



Dr. Heinrich Giegrich
Head of RA & Quality

Valid until: 2030-12-07

Table 1: Scope

REF	Description
831273	TRAUMA Bandage 10cm
831274	TRAUMA Bandage 15cm
831275	TRAUMA Bandage 20cm
831276	TRAUMA Bandage 10cm AR
831373	TRAUMA Bandage 10cm Scandinavia
831374	TRAUMA Bandage 15cm Scandinavia
831375	TRAUMA Bandage 20cm Scandinavia
831573	TRAUMA Bandage 10cm Southern Europe
831574	TRAUMA Bandage 15cm Southern Europe
831575	TRAUMA Bandage 20cm Southern Europe
831380	TRAUMA Bandage 10cm Taiwan
831390	TRAUMA Bandage 15cm Taiwan
831400	TRAUMA Bandage 20cm Taiwan
831673	TRAUMA Bandage 10cm UK
831674	TRAUMA Bandage 15cm UK
831675	TRAUMA Bandage 20cm UK