IVF HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Neuhausen, 2025-DEC-08

Product Group Number	**3560 Coop waterproof sterile dressing** (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 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	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	76116003560MX	
	Code	Term
EMDN	M040101	ADHESIVE DRESSINGS, WITH ABSORBENT PAD
GMDN	34864	Adhesive bandage
UMDNS	10-288	Bandages, Self-Adherent

IVF HARTMANN AG

i.V.

Andrea Marti
Senior Regulatory Affairs Manager

i.V.

Dr. Heinrich Giegrich
Head of RA & Quality

Valid until: 2030-DEC-07

Table 1: Scope

REF	Product code	Basic UDI-DI	Description
528000	3560	76116003560MX	Conviva Protect Steriler Wund. 10x8