

EU Declaration of Conformity

Neuhausen, 2025-DEC-08

Product Group Number	3338 Apoteket 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	76116003338MU	
EMDN	Code	Term
	M040101	ADHESIVE DRESSINGS, WITH ABSORBENT PAD
	34864	Adhesive bandage
	10-288	Bandages, Self-Adherent

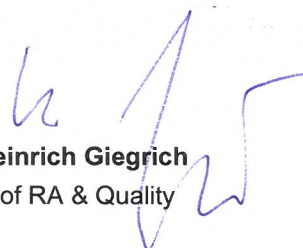
IVF HARTMANN AG

i.V.



Andrea Marti
Senior Regulatory Affairs Manager

i.V.



Dr. Heinrich Giegrich
Head of RA & Quality

Valid until: 2030-DEC-07



Helps. Cares. Protects.

Table 1: Scope

REF	Product code	Description
532585	3338	Apoteket Aqua Pfl. steril S
532586	3338	Apoteket Aqua Pfl. steril M