

EU Declaration of Conformity

Neuhausen, 2025-06-03

Product Group Number	3467 IVF Tricot Fingerling (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	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	76116003467N8	
EMDN	Code	Term
	M03030299	PROTECTION SYSTEMS - OTHER
GMDN	42050	Finger protector, reusable

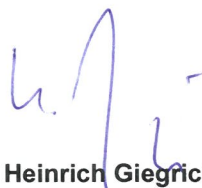
IVF HARTMANN AG

i.V.



Andrea Marti
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Dr. Heinrich Giegrich
Head of Regulatory & Quality

Valid until: 2030-JUN-30

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

REF	Description
833330	IVF Tricot Fingerling Gr3
833340	IVF Tricot Fingerling Gr4
833350	IVF Tricot Fingerling Gr5
833360	IVF Tricot Fingerling Gr6
833370	IVF Tricot Fingerling Gr7