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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Neuhausen, 2026-FEB-02

Product Group Number	**3466 IVF Armtraggurt** (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	General non-active non-implantable devices used in health care and other non-active non-implantable devices	
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	76116003466N6	
EMDN	Code	Term
	M030599	Immobilization Systems and Devices - Others
GMDN	67635	Arm immobilization sling, reusable

IVF HARTMANN AG

i.V.

Andrea Marti
Senior Regulatory Affairs Manager

i.V.

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
832410	IVF Armtraggurt schw Erw 185cmx35mm
832420	IVF Armtraggurt farb Erw 185cmx35mm
832470	IVF Armtraggurt farb Kind 150cmx35mm