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HARTMANN
Helps. Cares. Protects.

MDR Statement of System and Procedure Pack Producer

Neuhausen, 2024-09-02

We herewith declare under sole responsibility that the System and Procedure Packs listed in Table 1, first placed on the market by IVF HARTMANN AG, satisfy the applicable provisions described in Article 22 of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

We have verified the mutual compatibility of the devices and, if applicable other products, in accordance with their manufacturers' instructions and have carried out our activities in accordance with those instructions.

We package the System or Procedure Pack and supply relevant information to users incorporating the information supplied by the manufacturers of the devices or other products that are put together.

The activity of combining devices and, if applicable, other products, is subject to appropriate methods of internal monitoring, verification and validation.

Object of declaration:	**Garment Sets non-sterile covered in TD050009 (3703)**
Product(s):	See Table 1
Basic UDI:	76116003703MV
EMDN:	V0599
GMDN:	61938
EUDAMED Actor ID:	CH-PR-000019926
Swiss Single Registration Number:	CHRN-PR-20000307

IVF HARTMANN AG

i.V.

Andrea Marti
Senior Regulatory Affairs Manager

i.V.

Dr. Heinrich Giegrich
Head of RA & Quality

Valid until: 2026-JAN-07

Table 1: Scope

REF	Description
990500	Patienten-Set
990537	Patienten-Kit Gr M
990538	Patienten-Kit Gr L
990539	Patienten-Kit Gr XL
990573	Begrüssungs-Set 1
990574	HNO-Set
990587	Patienten-BE