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HARTMANN
Helps. Cares. Protects.

MDR Statement of System and Procedure Pack Producer

Neuhausen, 2026-JAN-07

We herewith declare under sole responsibility that the System and Procedure Packs listed below, first placed on the market by IVF HARTMANN AG, satisfy the applicable provides 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:	**Procedure Packs non-sterile covered in TD050001 (3782)**
Product(s):	See Table 1
Basic UDI	76116003782NK
Swiss Single Registration Number:	CHRN-PR-20000307
EU Single Registration Number:	CH-PR-000019926

IVF HARTMANN AG

i.V.

Andrea Marti

Senior Regulatory Affairs Manager

i.V.

Dr. Heinrich Giegrich

Head of RA & Quality

Valid until: 2029-SEP-30

Table 1: Scope

REF	EMDN	Description
831271	V0501	Trauma-Box-Beutel
831277	V0501	Trauma-Box-Beutel SCAND
990540	V0599	Sklero-Set m. st + ust Komponent.