**IVF HARTMANN AG**
Victor-von-Bruns-Strasse 28
Postfach 634
CH-8212 Neuhausen

+41 52 674 31 11
+41 52 672 74 41
info@ivf.hartmann.info
ivf.hartmann.info

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# MDR Statement of System / Procedure Pack Producer

Neuhausen, 25th of February 2022

We herewith declare,

**Object of declaration: Procedure Packs Garment Sets non-sterile covered in TD050009 (3703)**

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.

Product(s): See Table 1

GMDN: 61938

CND: See Table 1

EU Single Registration Number: CH-PR-000019926

Swiss Single Registration Number: CHRN-PR-20000307

IVF HARTMANN AG

i.V. Andrea Marina Marti
Regulatory Affairs Manager

Valid until (YYYY-MM-DD): 2026-01-07

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Table 1: Scope

| REF | Description | CND | Basic UDI-DI |
|---|---|---|---|
| 990573 | Begrüssungs-Set 1 | V0599 | 76116003703MV |
| 990574 | HNO-Set | V0599 | 76116003703MV |
| 990581 | Patienten-Set | V0599 | 76116003703MV |
| 990587 | Patienten-BE | V0599 | 76116003703MV |
| 990591 | Patienten-BE-Tagesklinik | V0599 | 76116003703MV |