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PRODUCT TECHNICAL DATA SHEET

MOD. 07 POS. 002 REV.00
DATA 23/06/2021

CE 0051

PRODUCT COMPOSITION:

The device consists of:

1. **2000 ml collection bag** in **PVC**, with non-return valve, "push-pull" drain tap, connection tube I.D. 5.2 mm x O.D. 6.5 mm and length cm 90;
2. **Male Luer Lock connector** in **ABS;**
3. **3-way stopcock (**360° rotation) made in **Polyethylene** and **Polycarbonate,** with fluid direction indicators to identify the different procedure phases (aspiration of pleural effusion from the patient; discharge into collection bag);
4. **Protective cap** in blue **ABS;**
5. **Female luer lock connector** in **ABS;**
6. **Tube** in **DEHP FREE PVC**, I.D. 4.8 mm x O.D. 6.8 mm and length cm 40;
7. **Vented cap** in **Polyethylene**;
8. **60 ml syringe** to be connected to the 3-way stopcock, made in **Polypropylene** and **Synthetic Isoprene rubber;**
9. **Stainless Steel 14G Needle** with a length of 55 or 80 mm (see table), packaged in microperforated bag;
10. **Stainless Steel 16G Needle** with a length of 55 or 80 mm (see table), packaged in microperforated bag**;**
11. **Stainless Steel 19G Needle** with a length of 55 or 80 mm (see table), packaged in microperforated bag**.**

INTENDED USE:

Closed circuit system thoracentesis, particularly suitable for the aspiration of pleural effusion liquid.
Following an evaluation by the healthcare professional, and under his direct control, the device can be used for paracentesis procedures.

PACKAGING:

Primary packaging: single device in micro-perforated **PE** inner pouch bag + blister in medical grade paper/**PP-PE** film.
Secondary packaging: carton with 30 pieces.

PRODUCTION PROCESS:

The device is manufactured in accordance with HMC Premedical S.p.A. Quality System and in comply with the requirements of the standard EN ISO 13485.

CONTROL ON THE PRODUCT:

In all stages of processing, according to internal procedures and to sampling plans defined by norm ISO 2859-1.

CLASSIFICATION:

Class IIa sterile.

STERILIZATION:

Product sterilized by ethylene oxide according to a validated course of treatment in accordance with current regulations.
Shelf life: **5 years** from the date of sterilization.
For single use only and non re-sterilizable.

STORAGE:

Standard storage procedures and conditions.

DISPOSAL:

The user must follow the legal regulations regarding disposal of hospital waste.

WARNINGS:

The device must be used exclusively by healthcare professionals.

REGISTRATION TO ITALIAN MEDICAL DEVICES REPERTOIRE:

CND: **A060204**
RDM: **1575159**
GMDN: **36787**

UNIT OF SALE:

Carton with **30 pieces**.

GTIN-UDI:

See table.