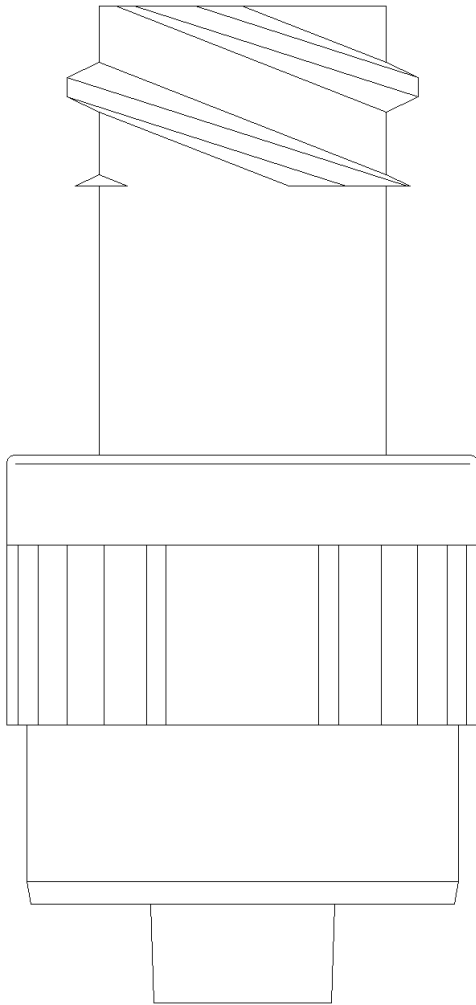


# PRODUCT TECHNICAL DATA SHEET

## DESCRIPTION M.L.L./F.L.L. STOPPER CAP



DEHP FREE

TABLE 1

CODE	COLOR	PACKAGING	CARTON
MCI/711	RED	Bag with <b>100 pcs.</b>	10 bags ( <b>1000 pcs.</b> )
MCI/711W	WHITE	Box with <b>100 pcs.</b>	4 boxes ( <b>400 pcs.</b> )

# PRODUCT TECHNICAL DATA SHEET

● **PRODUCT COMPOSITION:**

M.L.L./F.L.L. stopper cap in **Polypropylene**, available in white and red version.

● **INTENDED USE:**

Non-pierceable stopper cap for protection of medical devices endowed with F.L.L. and M.L.L. connectors.

● **PACKAGING:**

Primary packaging: single sterile product in medical paper/PP-PE film Blister.

Secondary packaging:

- **MCI/711** → pouch bag with 100 pcs; carton with 10 pouch bags (1000 pcs.);
- **MCI/711W** → box with 100 pcs; carton with 4 boxes (400 pcs.).

● **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: **A0701**

RDM: **327828**

GMDN: **N.D.**

● **UNIT OF SALE:**

See **TABLE 1** for details.

● **UDI:**

	SINGLE PRODUCT	POUCH BAG	BOX	CARTON
MCI/711	18053676290304	28053676290301	38053676290308	—
MCI/711W	18053676290076	—	38053676290070	58053676290074

REV.	CHANGES	ISSUED	VERIFIED AND APPROVED	DATE
00	First issue – English language	E. Benassi	D. Bosetti	19/09/2017
01	Packaging update	E. Benassi	S. Tralli	16/04/2020
02	Legal manufacturer address update	E. Benassi	S. Tralli	10/06/2021
03	Data sheets for MCI/711 and MCI/711W merged	E. Benassi	S. Tralli	09/07/2021
06	Data sheet update: jump to revision 6 to align with italian version	E. Benassi	S. Tralli	05/01/2022
07	Packaging update	E. Benassi	S. Tralli	31/05/2022