

TECHNICAL DATA SHEET

WHITE M.L.L./F.L.L. STOPPER CAP

● **PRODUCT COMPOSITION:**

M.L.L./F.L.L. stopper cap in white **Polypropylene**.

● **INTENDED USE:**

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

● **PACKAGING:**

Single package in Paper/PP-PE film Blister.
Boxes of 100 pieces, cartons of 400 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:**

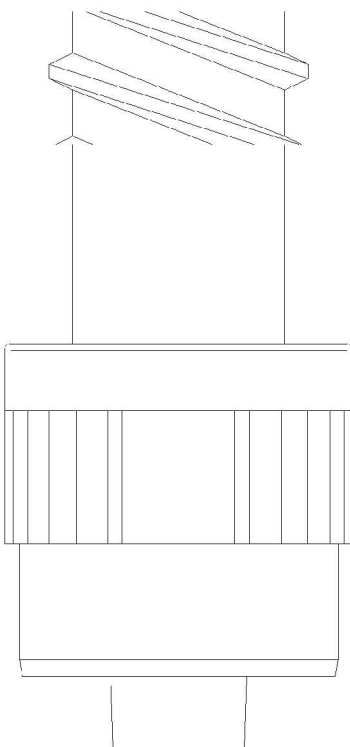
The user must follow the legal regulations regarding disposal of hospital waste.

● **WARNINGS:**

The device must be used exclusively by healthcare professionals.

● **REGISTRATION TO ITALIAN M.D. REPERTOIRE:**

nr. CND: **A0701** – nr. RDM: **327828**



DEHP FREE

CODE	BOX pcs.	CARTON pcs.
MCI/711W	100	400

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – English language	19/09/2017	E. Benassi	D. Bosetti
01	Data sheet revision – table updated	24/01/2019	E. Benassi	E. Benassi