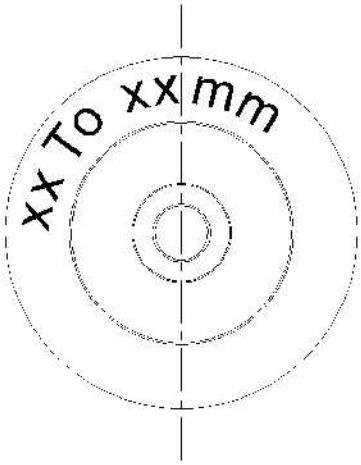
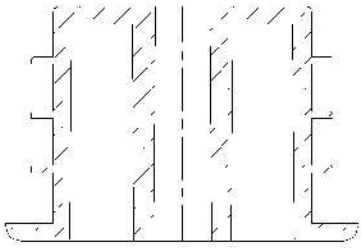
HMC Premedical S.p.A.
Via Tonino Morandi, 16 - 41037 MIRANDOLA (MO) ITALY Tel. 0535 22704 - Fax. 0535 609546 info@hmcgroup.it

CE 0051

TECHNICAL DATA SHEET
Purple ENFit bottle adapter





PRODUCT COMPOSITION:
Cap with **ENFit** adapter in purple **PE,** in various sizes (see table), produced in compliance with ISO 80369-3 norm.

INTENDED USE:
Preservation and drawing of bottled drugs.

PACKAGING:
Single packaging in Paper/PP-PE film Blister. Multiple package: 50 pcs.

PRODUCTION PROCESS:
The device is manufactured in accordance with the Quality System in compliance with the requirements of the standard EN ISO 13485.

CONTROL ON THE PRODUCT:
In all stages of processing, such as internal procedures and according to sampling plans according to ISO 2859-1.

CLASSIFICATION:
Class IIa sterile.

STERILIZZATION:
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:
CND: **A0880**
RDM: **1572532**

DEHP FREE

CODE	BOTTLE mm	BOX pcs.
BA02L	**15 ÷ 16,5**	50
BA03L	**18 ÷ 19,5**	50
BA04L	**25,5 ÷ 27**	50
BA05L	**18,5 ÷ 20,5**	50
BA06L	**20 ÷ 21,5**	50
BA07L	**10,5 ÷ 11**	50
BA08L	**16,5 ÷ 18**	50

REV. *Rev.*	*MODIFICHE* *Changes*	DATA *Date*	EMESSO *Issued*	*VERIFICATO e APPROVATO* *Verified and Approved*
00	First issue – English language	08/04/2016	E. Benassi	D. Bosetti
01	Medical device registration updated	23/06/2017	C. Ferrari	D. Bosetti
02	Data sheet revision; code BA08L added	03/09/2019	E. Benassi	E. Benassi