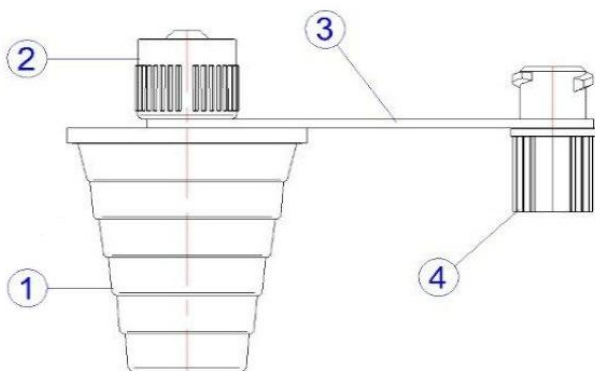


## SCHEMA TECNICA PRODOTTO

### Purple ENFit Universal bottle adapter



#### ● PRODUCT COMPOSITION:

1. Stepped bottle adapter in purple **DEHP FREE soft PVC**.
2. **ENFit** male connector in purple **ABS**, produced in compliance with ISO 80369-3 norm.
3. Strap  $\varnothing$  5mm in white **DEHP FREE PVC**.
4. Closed female **ENFit** cap in white **DEHP FREE PVC**, 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 (see table below).

#### ● 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.

#### ● 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:

no. CND: **A0880** – no. RDM: **1572532**

**DEHP FREE**



CODE	BOX pcs.
BA01L	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	Update of Classification and RDM number.	08/09/2017	E. Benassi	D. Bosetti
02	Data sheet revision	10/11/2017	E. Benassi	D. Bosetti