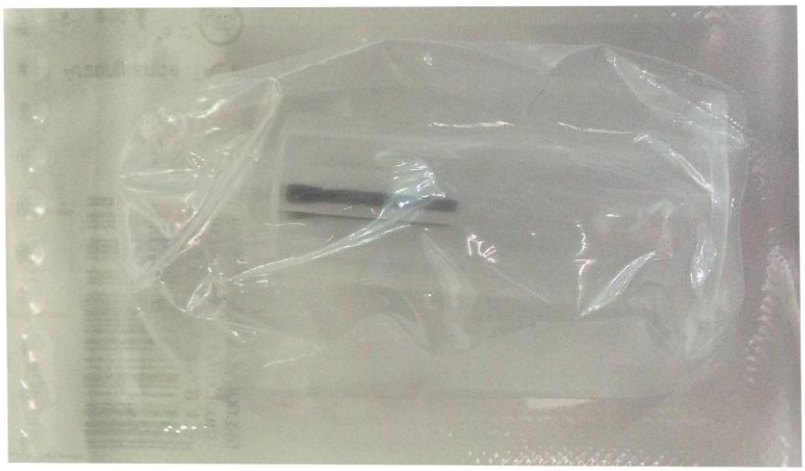
CODE	***DESCRIPTION***
1526537A	**STERILE LUER ADAPTER PREASSEMBLED ON HOLDER**

Each single device is packed is peel-pack bags.





IDENTIFICATION COLOR:

Holder and Luer Adapter: TRANSPARENT

SIZE AND FEATURES OF THE ADAPTER:

NEEDLE	
Material:	Stainless steel cannula AISI 304 special siliconized single point
Diameter:	External 0,90 mm – internal 0,60 mm
Length:	23,80 mm
LUER ADAPTER	
Material:	polypropylene
Diameter:	6,1 mm
Height:	22 mm
Hole of needle introduction:	1,00 mm
RUBBER SLEEVE	
Material:	Isoprene rubber gray
Average external diameter:	2,5 mm
Maximum length**:**	20,00 mm
PEEL PACK	Printed : REF – CE 0373 - manufacturer name – indication of safeness– sizes – sterilization – lot – expiring date

Specific size of the holder:	
Diameter: **Total Length:** **Length needle insertion :**	20 mm (cylindrical part) - 30,00 mm (base**)** 52,20 mm 4,50 mm
Nominal Validity :	
3 (three) years from the manufacturing date.	
Sterilization:	

With a treatment of ETO, in compliance with the rules :

UNI EN 556-1 Sterilization of medical devices- requirement for medical devices to be designated "sterile"- requirements for terminally sterilized medical devices.

UNI EN ISO 11135-1 ealth care products sterilization- Ethylene Oxide- Part 1: requirements for the development, validation and routine control of medical devices sterilization process.

UNI CEN ISO 11135-2 Sanitary products sterilization- Ethylene Oxide- Part 2: guide on application of ISO 11135-1 .
UNI EN 1422- Sterilizers for medical purpose- Ethylene Oxide sterilizers- requirements and test methods.

UNI EN ISO 11138-1 health care products sterilization- Biological indicators- Part 1: general requirements;
UNI EN ISO 11138-2 health care products sterilization- Biological indicators- Part 2: biological indicators for Ethylene Oxide sterilization processes;
UNI EN ISO 10993-7 Medical device biological evaluation- Part 7: Ethylene Oxide sterilization residual;

UNI EN ISO 11737-1 Medical devices sterilization- Microbiological methods- part 1: determination of a population of microorganism on products
UNI EN ISO 11737-2 Medical devices sterilization- Microbiological methods- part 2: tests of sterility performed in the definition, validation and maintenance of a sterilization process.

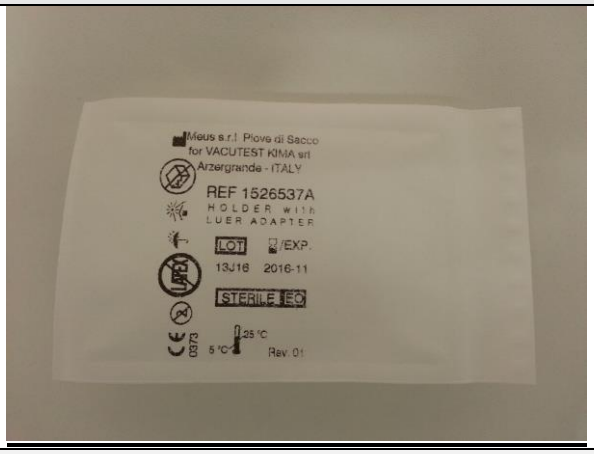
THE PRODUCT IS STERILE WITH A INDIVIDUAL PACKAGING

CERTIFICATIONS OF MATERIALS:

All the raw material and the material used, are not toxic, certified for food and medical use, according to the European and FDA (USA) lows.
According with information supplied for components manufacturers and with the implemented manufacturing process, the offered products are LATEX-FREE and PHT/DEHP FREE.

Print on individual packaging:

Sensitive data (code, lot, exp date, sterile EO) and instruction for use printed in the paper for individual packaging.



Packaging:

Middle packaging:

Internal box of 100 pcs

Inseparable external packaging:

Cartons of 400 pcs

Identification:

Middle packaging	***External packaging inseparable:***
Labels with REF, description, lot, expiry (year and month), code, q.ty, operator identification, sterilization type, production date and various symbols of use.	Labels with REF., description, lot, expiry (year and month), code, quantity, operator identification, sterilization type, production date and symbols of use.

Destination of use:

They are used for multiple sample collection of blood, from one single patient, with vacuum tubes.
The rubber sleeve is made of material suitable to perform an immediate return over the cannula after the blood collection and avoid any possible blood spilling.
This product must be used from qualified operators.

Storage and preservation:

The storage and preservation of the adapters for long time must be done at a certain temperature between +5 to +25 °C, in a dry place.

Disposal methods:

Before the use the products have to be consider not hazardous material as D.Lgs. 156/06 e s.m.i.

After the use become waste potentially infected that have to collect and disposed applying all particular precautions to avoid infections: CER 18 01 03

Manufacturing quality system and reference rules:

UNI EN ISO 9001:2015 certificate no. 4264/5/D issued by ICIM S.p.a.
UNI EN 13485:2016 certificate 4265/5/D issued by ICIM S.p.a.

UNI EN 15223-1 Graphical symbols used on medical devices labelling;

UNI EN 1041 Information supplied by the manufacturer for medical devices;

UNI CEI EN ISO 14971 application of risk management for medical devices ;

UNI EN ISO 6009 disposable hypodermic needles – identificative color codification;

CE: production quality system approval according with CE Directive 93/42/EC receipt with Italian legislative decree 46/1997 and following modifications- through the award of CE certificate no. 003 QPZ 858 09 dd 09/03/2009 Notify body 0373 issued by Italian Ministry of Health for MEUS S.R.L.-Via Leonardo da Vinci, 24/B- 35028 Piove di Sacco (PD).

Compatibility:

The STERILE LUER ADAPTER PREASSEMBLED ON HOLDER are going to be used with epidural needle (butterfly needle) for the collection of blood in one or more tubes (multiple drawing) with predetermined vacuum.

The STERILE LUER ADAPTER PREASSEMBLED ON HOLDER are compatible with the main systems present in the market.