



## **TECHNICAL DATAS OF SYRINGE 50/60ML FOR SINGLE USE**

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VICOLO 1° - 35036 MONTEGROTTO TERME (PD) – ITALIA

N° IDENTIFICATION CE: 0373

NUMBER OF THE CERTIFICATE: QPZ-1931-20

CLASS: IIa

CND / EMDN CLASSIFICATION: A020102020102

N° REGISTRATION REPERTORY D.M. : 59508 (Italian registration)

REF. PRODUCT: ML108C

LABEL: IMI

VOLUME: 50/60ML

NOZZLE: LUER LOCK

BARREL: ATOXIC POLYPROPYLENE ADDED OF MASTER BATCH ORANGE COLOR

PLUNGER: POLYPROPYLENE ATOXIC ADDED OF MASTER BATCH WHITE COLOR

SEAL GASKET DOUBLE RING: MADE OF SYNTHETIC POLYSOPRENE BLACK COLOR

SCALE: MARKED EACH ML IN BLUE COLOR FOR DRYING PROCESS BY UV LED

SILICONIC OIL: MEDICAL FLUID

PRIMARY PACKAGE: BLISTER OF MEDICAL PAPER AND COUPLED FILM

SECONDARY PACKAGE: BOX OF TRIPLE CARTON RECYCLABLE x 50 PCS cm 38.0x19.5x19.5

OUTSIDE CARTON: TRIPLE CARTON RECYCLABLE x 300 PCS cm 60.0x39.0x42.0

STERILIZATION: BY ETHYLENE OXYDE

SHELF LIFE: 5 YEARS

DELIVERY: ON PALLETT 120x80x220 INCLUDING 20 OUTSIDE CARTONS

MANUFACTURE: ACCORDING TO A QUALITY SYSTEM THAT ACCOMPLISHES ANNEX V° OF DIRECTIVE  
93/42/CEE

**NOTE: SYRINGES ARE PVC FREE, LATEX FREE.**

**ALL USED SUBSTANCES ACCOMPLISH WITH REGULATION EC 1907/2006 REACH.**

### **INSTRUCTION FOR USE:**

1. Sterile only in undamaged package.
2. Use the syringe immediately after the aspiration of the fluid.
3. Move the plunger only in sterile place.
4. Single use.
5. Do not sterilize again.
6. Throw away syringe after use.

### **STABILITY:**

Stock of products: keep the material in cool and dry place (temperature +5 ...+35°C – H.R. 30/70%)

For the protection from bright sources is sufficient to keep the product in its blister.

### **INTENDED USE:**

Injection therapy and infusional therapy (on driven syringes' pump) with light sensitive liquids

ACCORDING TO THE FOLLOWING STANDARDS:

ISO 80369-7

ISO 7886-1

ISO 7886-2 (**COMPATIBLE WITH PUMP'S SETTING MONOJECT**)

ISO 10993

UNI EN ISO 11135

UNI EN ISO 556

EUROPEAN PHARMACOPOEIAE

EUROPEAN DIRECTIVE 93/42 CEE



# 300 STERILE SYRINGES 50/60 ml

MEDICAL DEVICES

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<p>SEFRANÇAS ESTERILIZADAS A USAGE UNIQUE</p> <ul style="list-style-type: none"> <li>• Conformes à la pharmacopée européenne.</li> </ul>	<p>STERILE DISPOSABLE SYRINGES</p> <ul style="list-style-type: none"> <li>• European Pharmacopoeia.</li> </ul>	<p>STERILE INJAL</p> <ul style="list-style-type: none"> <li>• European Pharmacopoeia.</li> </ul>	<p>SERINGUILLAS ESTERILES DESCARGABLES</p> <ul style="list-style-type: none"> <li>• En conformite con la farmacopea Europea.</li> </ul>	<p>SERINGHE STERILE MONOUSO</p> <ul style="list-style-type: none"> <li>• In conformitate cu Farmacopeea Europei.</li> </ul>
<p>SPUITEN VOOR EENMALIG GEBRUIK</p> <ul style="list-style-type: none"> <li>• Conform aan de Europese farmacopée.</li> </ul>	<p>APARELHOS PARA INJEÇÃO ÚNICA</p> <ul style="list-style-type: none"> <li>• Conformes à la pharmacopée européenne.</li> </ul>	<p>STERIL ENJANGOSPRUITOR</p> <ul style="list-style-type: none"> <li>• En conformitate cu Farmacopeea Europei.</li> </ul>	<p>STERIL SPROUITE TI ENJANGOSBRUG</p> <ul style="list-style-type: none"> <li>• Conformitate cu Farmacopeea Europei.</li> </ul>	<p>STERILIGENT KERTAKAYITIMLIKAVUT</p> <ul style="list-style-type: none"> <li>• Avrupa Birliği Farmakopesi ile uyumlu.</li> </ul>


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