



TECHNICAL DATAS OF SYRINGE 50/60ML FOR SINGLE USE

MANUFACTURER: I.M.I. SNC DI MAZZUCATO PAOLO, ENRICO & C. – VIALE DELL'ARTIGIANATO
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: ML90L

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 594-1

ISO 594-2

ISO 7886-1

ISO 7886-2 (COMPATIBLE WITH PUMP'S SETTING TERUMO 50)

ISO 10993

UNI EN ISO 11135

UNI EN ISO 556

EUROPEAN PHARMACOPOEIAE

EUROPEAN DIRECTIVE 93/42 CEE



50 STERILE SYRINGES 50/60 ml FOR SINGLE USE

- F** SERINGUES STERILES A USAGE UNIQUE
 - Conformes à la pharmacopée Européenne.
- GB** STERILE DISPOSABLE SYRINGES
 - According to European pharmacopoeia.
- D** STERILE EINMAL SPRITZEN
 - Europäischem apothekisch gleichförmig.
- E** JERINGUILLAS ESTERILES DESECHABLES
 - En conformidad con la farmacopea Europea.
- I** SIRINGHE STERILI MONOUSO
 - In conformità con la farmacopea Europea.
- P** SERINGAS ESTERES DESCARTAVES
 - Em conformidade com a farmacopeia Europeia.

- NL** SPUITTEN VOOR EENMALIG GEBRUIK
 - Conform aan de Europese farmacopee.
- GR** ΑΠΟΧΡΩΜΕΝΩΣ ΣΥΡΙΓΓΗΣ ΜΙΑΣ ΧΡΗΣΗΣ
 - Συμβαίει με την Ευρωπαϊκή φαρμακοποιία.
- S** STERILA ENGANGSSPRUTOR
 - Enligt europeisk farmakopé.
- DK** STERIL SPRØJTE TIL ENGANGSBRUG
 - Lovensstemmelse med Eur. Ph.
- SP** STERILODUT KERTAKAYTORUSKUT
 - Eurooppalaisen farmakopien mukaisesti.
- SA** حقنات معقمة احادية الاستخدام
 - حياطة الوارد العربية.

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MEDICAL DEVICES



869



300 STERILE SYRINGES 50/60 ml

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MEDICAL DEVICES

<p>SEFRANÇAS ESTERILIZADAS USAGEM ÚNICA</p> <ul style="list-style-type: none"> • Condições de armazenamento especiais. 	<p>STERILE DISPOSABLE SYRINGES</p> <ul style="list-style-type: none"> • Condições de armazenamento especiais. 	<p>STERILE SINGLE ENGANGSSPRUITEN</p> <ul style="list-style-type: none"> • Condições de armazenamento especiais. 	<p>SEFRANÇILLAS ESTERILIZADAS DESCARGABLES</p> <ul style="list-style-type: none"> • En condiciones de almacenamiento especiales. 	<p>SPRINĖHE STERILE WONDROUDE</p> <ul style="list-style-type: none"> • En condiciones de almacenamiento especiales.
<p>SPUITEN VOOR EENMALIG GEBRUIK</p> <ul style="list-style-type: none"> • Condições an de stocagem especiais. 	<p>AJUSTEMENTOS ÚNICO USAGEM</p> <ul style="list-style-type: none"> • Condições an de stocagem especiais. 	<p>STERILE ENGANGSSPRUITEN</p> <ul style="list-style-type: none"> • En condiciones de almacenamiento especiales. 	<p>STERIL SPUGUITE TI ENLARGOSBRUG</p> <ul style="list-style-type: none"> • Condições an de stocagem especiais. 	<p>STERILGOUT KERTAKAYITONLAKUT</p> <ul style="list-style-type: none"> • En condiciones de almacenamiento especiales.

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