



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: TL90N

LABEL: IMI

VOLUME: 50/60ML

NOZZLE: LUER LOCK

BARREL: TRANSPARENT POLYPROPYLENE ATOXIC

PLUNGER: POLYPROPYLENE ATOXIC ADDED OF MASTER BATCH WHITE COLOR

SEAL GASKET DOUBLE RING: MADE OF SYNTHETIC POLYSOPRENE BLACK COLOR

SCALE: MARKED EACH ML IN BLACK 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)

ACCORDING TO THE FOLLOWING STANDARDS:

ISO 591-1

ISO 594-2

ISO 7886-1

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

ISO 10993

UNI EN ISO 11135

UNI EN ISO 556

EUROPEAN PHARMACOPOEIAE

EUROPEAN DIRECTIVE 93/42 CEE



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STERILES A
USAGE UNIQUE

• Conformes à la pharmacopée Européenne.

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STERILE
DISPOSABLE
SYRINGES

• According to European pharmacopoeia.

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• Europäischem apothekisch gleichförmig.

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• En conformidad con la farmacopoea Europea.

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SIRINGHE
STERILI
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• Conform aan de Europese farmacopoe.

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ΣΥΡΙΓΓΗ ΜΙΑΣ
ΧΡΗΣΗΣ

• Συμφωνία με την Ευρωπαϊκή φαρμακοποία

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• Enligt europeisk farmakopé

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STERIL SPROEJTE
TIL ENGANGSBRUG

• Lovensstemmelse med Eur. Ph.

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STERILODUT
KERTAKAYTÖRUSKUT

• Eurooppalaisen farmakopien mukaisesti.

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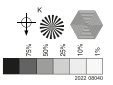
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MEDICAL DEVICES



869

300 STERILE SYRINGES 50/60 ml

MEDICAL DEVICES

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MEDICAL DEVICES

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<p>SPUITEN VOOR EENMALIG GEBRUIK</p> <ul style="list-style-type: none"> • Conform aan de Europese richtlijn. 	<p>APPAREILS UNIFORMES STERILES MAL USAGE</p> <ul style="list-style-type: none"> • Conformes à la réglementation européenne. 	<p>STERIL ENJANGOSPRUITOR</p> <ul style="list-style-type: none"> • Este dispozitiv este în conformitate cu legislația europeană. 	<p>STERILGÖZÜLT KERTAKAYITTIHARLIKAT</p> <ul style="list-style-type: none"> • Avrupa Birliği Direktifi ile uyumludur. 	<p>سرنجچه‌های استریل یکبار مصرف</p> <ul style="list-style-type: none"> • متوافق مع دستورالعمل اروپایی.

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