



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: A020102020101

N° REGISTRATION REPERTORY D.M. : 59510 (Italian registration)

REF. PRODUCT: MP98NA

LABEL: IMI

VOLUME: 50/60ML

NOZZLE: LUER LOCK PERFUSION

MOUNTED NEEDLE: 14G

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 38.0x24.5x19.5

OUTSIDE CARTON: TRIPLE CARTON RECYCLABLE x 300 PCS cm 60.0x39.0x49.5

STERILIZATION: BY ETHYLENE OXYDE

SHELF LIFE: 5 YEARS

DELIVERY: ON PALLETT 120x80x210 INCLUDING 16 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 B.BRAUN PERFUSOR**)

ISO 10993

UNI EN ISO 11135

UNI EN ISO 556

EUROPEAN PHARMACOPOEIAE

EUROPEAN DIRECTIVE 93/42 CEE



STERILE SYRINGES

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

- Europäischen spritzen gleichmäßig.

E
JERINGUILLAS
ESTERILES
DESCARTABLES

- En conformidad con la farmacopoea Europea.

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SPRINCHJE
STERIL
MONDOUSO

- In conformita con la farmacopoea Europea.

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SERINGAS
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- En conformidade com a farmacopoea Europeia.

NL
SPUITEN
VOOR EENMALIG
GEBRUK

- Conform aan de Europese farmacopoe.

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AIDHTÉIPOMENÉZ
SYRITZES MIÁZ
XRFHILÉ

- Συμμόρφη με την Ευρωπαϊκή φαρμακοποιία.

S
STERILA
ENGANGSSPRUTOR

- Enligt europeisk farmakopé.

GB
STERIL SPROEITE
TI. ENGANGSBRUG

- I overensstemmelse med Eur. Ph.

SP
STERIL OJOUT
KERTAKÄYTTÖKESKUT

- Eurooppalisen farmakopieen mukaisesti.

SA
معدات طبية
احادية الاستخدام

- هذا الجهاز احادية الاستخدام الأوروبية

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MEDICAL DEVICES

STERILE EO MD



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