



## **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: TP98NA

LABEL: IMI

VOLUME: 50/60ML

NOZZLE: LUER LOCK PERFUSION

MOUNTED NEEDLE 14G

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 BLU 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)**

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 a la farmacopea Europea.

**GB**  
STERILE  
DISPOSABLE  
SYRINGES

- According to European pharmacopeia.

**D**  
STERILE  
EINMAL  
SPRITZEN

- Europäischem spritzen gleichförmig.

**E**  
JERINGUILLAS  
ESTERILES  
DESCARTABLES

- En conformidad con la farmacopea Europea.

**I**  
SPRINCHJE  
STERIL  
MONDOUSO

- In conformità con la farmacopea Europea.

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SERINGAS  
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- En conformidade com a farmacopeia Europeia.

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SPUITEN  
VOOR EENMALIG  
GEBRUIK

- Conform aan de Europese farmacopee.

**GB**  
AIDHTÉAROMHÉIZ  
SYRITZIZ MIAZ  
XIFHIZ

- Suidhifis aic tithy fharmaiceolaíochais Eorpacha.

**S**  
STERILA  
ENGANGSSPRUTOR

- Enligt europeisk farmakopé

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STERIL SPROEITE  
TI. ENGANGSBRUG

- I overensstemmelse med Eur. Ph.

**SP**  
STERIL OJOUT  
KERTAKÄYTTÖRÖISKUT

- Eurooppalaisten farmakopean mukaisesti.

**SA**  
معدات طبية  
احادية الاستخدام

- هذا الجهاز احادية الاستخدام الأوروبية

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## MEDICAL DEVICES

STERILE EO MD



863



