



## **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: ML90NA

LABEL: IMI

VOLUME: 50/60ML

NOZZLE: LUER LOCK

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 594-1

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



## 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 gleichmäßig.

**E**  
JERINGUILLAS  
ESTERILES  
DESCARTABLES

- En conformidad con la farmacopea Europea.

**I**  
SPRINGHE  
STERIL  
MONDOUSO

- In conformità con la farmacopea Europea.

**P**  
SERINGAS  
ESTERIS  
DESCARTAVES

- En conformidade com a farmacopeia Europeia.

**NL**  
SPUITEN  
VOOR EENMALIG  
GEBRUIK

- Conform aan de Europese farmacopee.

**GB**  
AIDHTÉAROMHÉIZ  
SYRITZES MIAZ  
XHEID

- Suidáirís a tús fáilteannaí fáilteannaí.

**S**  
STERILA  
ENGANGSSPRUTOR

- Enligt europeisk farmakopé.

**GB**  
STERIL SPROEITE  
TE ENGANGSBRUG

- I overensstemmelse med Eur. Ph.

**SP**  
STERIL OJUNT  
KERTAKÄYTTÖKESKUT

- Eurooppalisen farmakopean mukaisesti.

**SA**  
معدات طبية  
احادية الاستخدام

- هذا الجهاز احادية الاستخدام العربية

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## MEDICAL DEVICES

STERILE EO MD



863



