



# TECHNICAL DATAS OF SYRINGE 50/60ML FOR SINGLE USE

MANUFACTURER: I.M.I. SNC DI MAZZUCATO PAOLO, ENRICO & C. - VIALE DELL'ARTIGIANATO VICOLO I° - 35036 MONTEGROTTO TERME (PD) - ITALIA

N° IDENTIFICATION CE: 0373

NUMBER OF THE CERTIFICATE: QPZ-1931-20

CLASS: Ila

CND / EMDN CLASSIFICATION: A020102020102

N° REGISTRATION REPERTORY D.M.: 59508 (Italian registration)

REF. PRODUCT: ML108N

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 PC\$ 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:**

- Sterile only in undamaged package. 1.
- Use the syringe immediately after the aspiration of the fluid.
- Move the plunger only in sterile place.
- 4. Single use.
- Do not sterilize again. 5.
- 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.D. PLASTIPAK)

ISO 10993 **UNI EN ISO 11135** UNI EN ISO 556

**EUROPEAN PHARMACOPOEIAE EUROPEAN DIRECTIVE 93/42 CEE** 



