



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: A020102020101

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

REF. PRODUCT: TL99NA

LABEL: IMI

VOLUME: 50/60ML NOZZLE: LUER LOCK 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 GREEN 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.

<u>STABILITY:</u>

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 B.BRAUN OMNIFIX)

ISO 10993

UNI EN ISO 11135

UNI EN ISO 556

EUROPEAN PHARMACOPOEIAE

EUROPEAN DIRECTIVE 93/42 CEE



