



TECHNICAL DATA SHEET

ZAMAR NO TOX LIQUID

ZAMAR PROPRIETARY LIQUID - code 3LIQ010

Description: Liquid supplied with ZAMAR systems that guarantees heat exchange between the patient and the DM.

Applications: The liquid circulates inside the bands, which are the physical means by which the therapy is delivered. The bands transmit the set temperatures locally.

Codes: 3LIQ010

Primary Device Codes: ZTCUBE MG465A / ZTCLINIC MG675A / ZCCAREPACE MG465B / MG455A (Z-ONE) / MG655A (ZHC)

Composition: Double-distilled water, monopropylene glycol (PAKELO - NO TOX FREEZE F)

STORAGE

- The product must be stored in an environment with a temperature range between +10°C and +40°C, relative humidity between 10% and 60%, and protected from light sources.
- The product, under the conditions described above, has a shelf life of 5 years from the date of sterilisation.

IDENTIFICATION LABEL

The label visible on each individual product contains the following information:

- product code
- volume
- description
- warnings
- manufacturer

COMPLIANCE REQUIREMENTS FOR THE PRIMARY MEDICAL DEVICE

- ZAMAR MEDICAL is UNI EN ISO 13485:2016 certified
- The device complies with the applicable requirements of Directive 93/42/EEC, Annex II excluding point 4, implemented in Italy by Legislative Decree 46 of 24/02/1997.
- The primary device is medical class IIa.
- The materials used in the construction of the device are NON-TOXIC
- Declaration of Conformity available upon request

MANUFACTURING FACILITY

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