

TECHNICAL DATA SHEET

Thermal Bands

Applied Parts Zamar Medical Medical Device

DESCRIPTION: Controlled compression bands are applied parts of the Zamar Medical system and are therefore supplied with the electro-medical device (Zamar Medical heat exchange equipment for cryotherapy and thermotherapy).

Applied part type BF

APPLICATIONS: the bands are the physical means by which the therapy is delivered: the bands transmit the set temperatures locally.

CODES: 1ACS261 / 1ACS262 / 1ACS263 / 1ACS281 / 1ACS282 / 1ACS266 / 1ACS267 / 1ACS268 / 1ACS269 / 1ACS270 / 1ACS272 / 1ACS273 / 1ACS279 / 1ACS283 / 1ACS284 / 1KITBUS001 / 1KITBUS002 / 1KITBUS003 / 1KITBUS004 / 1KITBUS005 / 1KITBUS006 / 1KITBUS007 / 1KITBUS008 / 1KITBUS009 / 1KITBUS010 / 1KITBUS011 / 1KITBUS012 / 1KITBUS013 / 1KITBUS014 / 1KITBUS015 / 1KITPAD001 / 1KITPAD002 / 1KITPAD003 / 1KITPAD004 / 1KITPAD005 / 1KITPAD007 / 1KITPAD008 / 1KITPAD009 / 1KITPAD011

Primary DM models: ZTCUBE / ZTCLINIC / ZCCAREPACE / Z-ONE / ZHC

CONTACT MATERIALS: 100% PU

MATERIALS USED IN THE APPLICATION PART: 100% PL (Felt)
100% PU (Coil) Inhibited
Propylene Glycol

STERILISATION: Ethylene oxide only upon request.

PACKAGING

- **Primary:** customised medical paper envelope with grid pattern
- **Secondary:** customised Zamar box

STORAGE

- The product must be stored in an environment with a temperature range between +10°C and +40°C and relative humidity between 10% and 60%, and protected from light sources.
- Under the conditions described above, the product has a shelf life of 1 year or 200 applications from the date of first use. If the product is sterile, its shelf life is 5 years. In this case, the applied part is to be considered disposable.

IDENTIFICATION LABEL

The following information can be found on the label visible on the packaging box and on each individual device:

- product code
- production batch
- date of manufacture
- "type of sterilisation" (if applicable)
- expiry date (if applicable)
- bar code

MEDICAL DEVICE COMPLIANCE REQUIREMENTS

- ZAMAR MEDICAL is UNI EN ISO 13485:2016 certified
- ZAMAR MEDICAL is certified UNI EN ISO 9001:2015
- 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 device is classified as medical class IIa.
- The materials used in the construction of the device are NON-TOXIC and NON-HAZARDOUS.
- Declaration of Conformity available upon request

MANUFACTURING FACILITY

- ZAMAR MEDICAL d.o.o. - Sv. Martin, 6 52450 Vrsar (PU) - Croatia