

DATA SHEET

ZAMAR MEDICAL

Heat exchange equipment, used for Cryotherapy and Thermotherapy

Description:

Active therapeutic device for cryotherapy and thermotherapy. Electromedical device powered by the network that allows localized heat exchanges to the interested parties through thermal wraps in physical contact (conduction), and therefore an increase (exogenous thermo-therapy) or a lowering (cryotherapy) of the temperature of the desired parts of the body, possibly associated with a surface massage.

Intended use:

Cryotherapy and Thermotherapy. Intended to supply energy, intended to come into contact directly only with the patient's intact epidermis, for temporary or exceptionally short-term use, in a not potentially dangerous manner.

Code: MG455B - MG465A - MG655A - MG675A

Class: IIa:

GMDN: 60707

Applied Parts:

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

Intended use:

The wraps constitute the physical medium through which the therapy is delivered. Non-invasive device.

Class: I

Code: 1ACS - 1PAD - 1BUS - 1KITBUS

STORAGE

- The product must be stored in an environment with temperature ranges between + 10 °C + 40 °C relative humidity 30% 60%
- the product under the conditions described above has a shelf life of 5 years

IDENTIFICATION LABEL

The following information is identifiable in the label visible on the packaging box and on each individual device:

- Model
- Year of manufacture
- Serial number - LOT
- Specifications

MEDICAL DEVICE CONFORMITY REQUIREMENTS

- ZAMAR is UNI EN ISO 13485: 2016 certified
- the device complies with the applicable requirements of Directive 93/42/EEC, Annex II excluding point 4,
- the materials used for the construction of the device are in conformity with 2011/65/UE (ROHS II)
- the materials used for the construction of the device are in conformity with CE1907/2006 (REACH)
- Declaration of Conformity available on request
-

PRODUCTION WORKSHOP

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