



DECLARATION OF COMPLIANCE



Manufacturer:

Name: DISPOTECH SRL
Address: GORDONA (SO)- VIA AL PIANO, 29
VAT number: 00672170149
R.E.A.: 47213

DECLARES

under its own responsibility that the product: INSTANT ICE BAGS

satisfies all the essential requirements as recommended in the Directive 93/42/EEC (Medical Devices) and successive modifications (included directive 2007/47/EC).

Classe of Medical Device: IIa enclosure IX rule 9

In accordance with harmonized standard:

European Directive 93/42/EEC and successive modifications (included European Directive 2007/47/EC)
REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices
MEDDEV 2.12-1 rev.8 Guidelines on a medical devices vigilance system
UNI EN ISO 13485:2016 European harmonized standard for medical device quality management system
UNI CEI EN ISO 15223-1:2017 Symbol to be used with medical device labels, labelling and information to be supplied
UNI CEI EN ISO 14971:2020 Application of risk management to medical devices
UNI CEI EN 1041:2013 Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2018 Biological evaluation of medical devices
MEDDEV 2.7.1 Clinical Evaluation: a guide for manufacturers and notified bodies
Regulation EC No. 1907/2006 of the European Parliament and of the council of 18 December 2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) (included regulation EC No. 552/2009)

CE certificate no.: 26556

Notified body no.: 0546 CERTIQUALITY SRL- Via Gaetano Giordano, 4- 20123 MILANO- ITALY

First issue: 20/02/2004

Current issue: 22/03/2021

Place: Gordona

Legal Representative
(responsible for the release of the product)

Date 24/01/2024

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