



**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)  
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**

**Expiry date: 28/01/2024**

Place: Gordona

Date 24/03/2021

Legal Representative  
(responsible for the release of the product)

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