



**DECLARATION OF COMPLIANCE**  
**CE**

**Manufacturer:**

Name: DISPOTECH SRL  
Address: CHIAVENNA (SO)- VIA MARIO DEL GROSSO, 8/12  
VAT number: 00672170149  
R.E.A.: 47213

**DECLARES**

**under its own responsibility that the product: INSTANT ICE BAGS EASY ICE, IMPLANT ICE**

**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 3/93-rev. 2 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 ed. 2012 "Symbol to be used with medical device labels, labelling and information to be supplied  
UNI CEI EN ISO 14971:2012 Application of risk management to medical devices  
UNI EN 1041:2013 Information supplied by the manufacturer of medical devices  
UNI EN ISO 10993-1:2010 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: 29/01/2019**

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

Place: Gordona

Legal Representative  
(responsible for the release of the product)

Date 05/02/2019



**Dispotech srl**

Sede operativa: 23020 GORDONA (SO) Via al piano, 29 - Tel. +39 0343 36711 - Fax. +39 0343 36367 - www.dispotech.com  
Sede legale: 23022 CHIAVENNA (SO) Via M. Del Grosso, 8/12 - e-mail: info@dispotech.it - PEC: dispotech@legalmail.it  
Cap Soc. € 1.500.000,00 i.v. - P. IVA 00672170149 - R.E.A. 47213 C.C.I.A.A. di SO - Uff. Reg. Imp. SO 00672170149