



EU DECLARATION OF CONFORMITY

Manufacturer:

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

SRN: IT-MF-000010735

DECLARES under its own responsibility that the product: WERO MINI, MIDI, MAXI INSTANT ICE BAGS

PRODUCT CODE: SF0854WERO; SF1854WERO; SF2454WERO

INTENDED PURPOSE: Haematomas, sprains, injuries, hyperthermia and whenever cold application is required

BASIC UDI-DI: ++G066SFDIS6Z

satisfies all requirements of **REGULATION (UE) 2017/745** related to Medical Devices.

Class of Medical Device: IIa, annex VIII rule 9

In accordance with standard:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

UNI CEI EN ISO 13485:2021 European harmonized standard for medical device quality management system

UNI CEI EN ISO 15223-1:2021 Symbol to be used with medical device labels, labelling and information to be supplied

UNI CEI EN ISO 14971:2022 Application of risk management to medical devices

UNI CEI EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer

UNI EN ISO 10993-1:2021 Biological evaluation of medical devices

CE certificate n.: ITD 1344523 1

Issued by Notified Body n: 1936 TÜV Rheinland Italia srl – Via Mattei, 3 - 20005 - Pogliano Milanese (MI), Italy

Conformity procedure in accordance with Annex XI part A of Regulation (EU) 2017/745

First issue: 29/07/2024

Validity: from 29/07/2024 to 29/07/2029

Place: Gordona

Legal Representative - Massimo Mortarotti
(responsible for the release of the product)

Date_05/02/2026_____

DISPOTECH S.R.L.
Via Al Piano, 29
23020 GORDONA (SO)
Tel. 0339 0343 36711 Fax 0339 0343 36567
Codice Fiscale e Partita Iva 00672170149

Dispotech srl Via al piano, 29 23020 GORDONA (SO) Italia

Tel. +39 0343 36711 - Fax. +39 0343 36567 - e-mail: info@dispotech.it - www.dispotech.com

Cap Soc. € 1.500.000,00 i.v. - P. IVA 00672170149 - SDI BA6ET11 - R.E.A. 47213 C.C.I.A.A. di SO - Uff. Reg. Imp. SO 00672170149