



YOUR DISPOSABLE EXCELLENCE



EU DECLARATION OF CONFORMITY

Manufacturer:

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

SRN: IT-MF-000010735

DECLARES under its own responsibility that the product: DISPOGEL REUSABLE COLD AND HOT GEL BAG

PRODUCT CODE: SG24DISPOGEL, SG18DISPOGEL, SG12DISPOMG, SG11DISPOGEL, SG26DISPOGEL, SG1726DISPOC20

INTENDED PURPOSE: Thermal therapy devices

UDI-DI di BASE: ++G066SGDIS78

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

Classe of Medical Device: I, allegato VIII regola 1

In accordance with harmonized 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 13485:2016 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 14971:2020 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

Place: Gordona

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

Date 31/01/2022

DISPOTECH S.R.L.
Via Al Piano, 29
23020 GORDONA (SO)
Tel. 0343 36711 Fax 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

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