



**YOUR DISPOSABLE EXCELLENCE**



## UE DECLARATION OF CONFORMITY

**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: 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 EN ISO 13485:2016 European harmonized standard for medical device quality management system

UNI CEI EN ISO 15223-1 "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 24/05/2021

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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