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

SRN: IT-MF-000010735

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

PRODUCT CODE: SG18MEDIFLEX, SG26MEDIFLEX

INTENDED PURPOSE: Thermal therapy devices

UDI–DI di BASE: ++G066SGDIS78

satisfies all the safety and performance 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

Date_26/09/2022____

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

DISPOTECH S.R.L
Via Al Piano, 29
23020 GORDONA (SO)
Tel. 0039 0343 36711 Fax 0039 0343 36567
Codice Fiscale e Partita Iva 00672170149