YOUR DISPOSABLE EXCELLENCE

EU DECLARATION OF CONFORMITY

The Manufacturer:

Name: DISPOTECH SRL
Address: GORDONA (SO)- VIA AL PIANO, 29
VAT NUMBER: 00672170149

SRN: IT-MF-000010735

DECLARES under its own responsibility that the product: *GIMA* ICE SPRAY

PRODUCT CODE: *SP400GIMA12*

INTENDED USE: alleviation of pain caused by traumatic injuries such as trauma, bruises, falls or sprains and in cases requiring cryotherapy and application of cold

BASIC UDI–DI: ++G066SPDISYT

Complies with Regulation (EU) 2017/745 related to Medical Devices.

Class of Medical Device: IIa, annex VIII rule 9

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 :2021 Medical devices - Quality management systems - Requirements for regulatory purposes
UNI CEI EN ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements
UNI CEI EN ISO 14971:2022 Medical devices - 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 — Part 1: Evaluation and testing within a risk management process
LEGISLATIVE DECREE 14 MARCH 2003 n°65 Implementation of Directives 1999/45/EC and 2001/60/EC relating to the classification, packaging and labelling of dangerous preparations
COMMISSION DIRECTIVE 2013/10/EU of 19 March 2013 amending Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers in order to adapt its labelling provisions to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
Commission Directive (EU) 2016/2037 of 21 November 2016 amending Council Directive 75/324/EEC as regards the maximum allowable pressure of aerosol dispensers and to adapt its labelling provisions to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers
AEROSOL standards AIA (Aerosol Italian Association)

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

Issuing date:_ 08/01/2025____

Legal Representative - Massimo Mortarotti
(responsible for product release)

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