



YOUR DISPOSABLE EXCELLENCE



DECLARATION OF COMPLIANCE



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: ICE SPRAY

satisfies all the essential requirements as recommended in the Directive 93/42/EEC (Medical Devices) and successive modifications (included directive 2007/47/EC).

Classe of Medical Device: IIa enclosure IX rule 9

In accordance with harmonized standard:

- European Directive 93/42/EEC and successive modifications (included European Directive 2007/47/EC)
- MEDDEV 2.12-1 rev.8 Guidelines on a medical devices vigilance system
- UNI EN ISO 13485:2016 European harmonized standard for medical device quality management system
- UNI CEI EN ISO 15223-1:2017 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
- ISO 10993-1:2018 Biological evaluation of medical devices
- MEDDEV 2.7.1 Clinical Evaluation: a guide for manufacturers and notified bodies
- 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
- Aerosol dispensers directive 75/324/EEC
- AIA aerosol directive

CE certificate no.: 26556

Notified body no.: 0546 CERTIQUALITY SRL- Via Gaetano Giordano, 4- 20123 MILANO- ITALY

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Place: Gordona

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Legal Representative
(responsible for the release of the product)

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