DECLARATION OF CONFORMITY

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Medical device:	**Ice Power Cold Spray**
Pack sizes	200 ml
Risk Class:	Class IIa as per the Rule 9 in Annex IX in Council Medical Device Directive 93/42/eec
Intended purpose	A non-sterile spray applied to intact human skin for cold therapy
Manufacturer's name:	Fysioline Oy
Business address:	Arvionkatu 2, FI-33840 Tampere, Finland
SRN No	FI-MF-000001173
DUNS Code	540106952
GMDN code and term:	46557 – Cold treatment spray
Notified Body	SGS Fimko Ltd (Notified Body No 0598)
Issued Certificate No	FI20/871789

Each kind of medical device to which the system has been applied to complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Standards applied:	EN ISO10993-1:2018 EN ISO13485:2016 EN ISO14971:2019 EN ISO15223-1:2016 Council Directive 93/42/EEC

We hereby declare that the above-mentioned device(s) comply with the legislation of the member state where the Notified Body located transposing European Medical Device Directive 93/42/EEC as modified by 2007/47/EC.

Authorised signature

FYSIOLINE OY fysioline TAMPERE FINLAND

Pertti Välikoski
Chairman of the Board
Fysioline Oy

Tampere, 11 March 2021
Date

Fysioline Oy
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