EC DECLARATION OF CONFORMITY

We, the undersigned, ensure and declare that the following products meet the provisions of the European Medical Device Directive 93/42/EEC which apply to them:

REF	Product name	1st SN	Last SN
MA1100-EU	Mistral-Air® Plus Forced Air Warming Unit (220-240V)	090500100	210370857
MA1100-US	Mistral-Air® Plus Forced Air Warming Unit (110-120V)	090700692	200570472
MA1200-EU	Mistral-Air® Warming Unit (220-240V)	170900234	
MA1200-US	Mistral-Air® Warming Unit (110-120V)	180302066	
MA1200-QC-EU	Mistral-Air® Warming Unit (220-240V)	190111942	
MA1200-QC-US	Mistral-Air® Warming Unit (110-120V)	190820733	

GMDN Code and Term: 36954 Circulating-air whole-body heating system Control unit

Classification: Class IIb (Annex IX, Rule 9)

Conformity assessment procedure: Annex II

Notified Body: DEKRA Certification B.V. (0344)
CE-certificate: 2081762CE04

Manufacturer:
Digitally signed by Grecu Mihnea Ioan
Date: 2024.06.14 09:49:44 EEST
Reason: MoldSign Signature
Location: Moldova

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Place and date of issue: Amersfoort , 2022-06-01

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