



natus

Natus Medical Denmark ApS
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**European Declaration of Conformity
to the Medical Device Directive, 93/42/EEC
as Amended by 2007/47/EC**



Declaration Number: 7-38-02850 Rev. 07
Product Name: ICS AirCal
See Appendix A
Product Model Number: Type 1079
GMDN code: 34891, *Caloric vestibular-stimulation system*
Description: Air Caloric Stimulator

Natus Medical Incorporated hereby declares that the above medical devices which bear the CE Mark are in conformity with the applicable requirements of EC Directive 93/42/EEC with amendments up to 2007/47/EC as enforced in the national laws of the European Union member states.

Classification/Rule: Class IIa, by Annex IX, Rule 10
Conformity Assessment Route: Annex II

This declaration is based on Certification of a full Quality Assurance System and compliance to the Medical Device Directive.

Certificate No.: 34748 rev. 1
Issued by: LNE/G-MED, CE 0459
Date: 26-May-2024

Additionally: Natus hereby declares, under its sole responsibility as Legal Manufacturer and not evaluated by the Notified Body listed above, that the product specified on this Declaration of Conformity is in conformity with Council Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. It has been demonstrated that the requirements specified in Article 4 of directive 2011/65/EU have been met.

This declaration of conformity is valid from 18-May-2020.

EU Authorized Representative:
N/A

Signature:  **date** 18May,2020
Sanjay Mehta, Director of Global Regulatory Affairs

Appendix A:

Part number	Description
8-62-44100	1079 Specula (Disposable)
8-04-13300	1079 AirCal Caloric Stimulator (Standard length - 3m)
8-04-13301	1079 AirCal Caloric Stimulator, Extended (Extended length - 4m)
8-04-13310	1079 AirCal Caloric Stimulator (Standard length - 3m), US only
8-04-13311	1079 AirCal Caloric Stimulator, Extended (Extended length - 4m), US only
8-04-13320	1079 AirCal Caloric Stimulator, Extended (Extended length - 4m), DS only
8-04-13330	1079 AirCal Caloric Stimulator, Extended (Extended length - 4m), CN only
8-04-13321	1079 AirCal (Standard length - 3m)
8-04-13322	1079 AirCal (Standard length - 4m)