natus

Natus Medical Incorporated
Natus Medical Denmark ApS
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Denmark, 2630

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

CE 0459

Declaration Number:	7-38-01416
Product Name:	MADSEN Astera MADSEN Astera with ACP MADSEN Astera 2 MADSEN Astera 2 with ACP
Product Model Number:	Type 1066
Description:	Clinical Audiometer with option Audiometer Control Panel (ACP)

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. 0
Issued by:	LNE/G-MED, CE 0459
Date:	24-Sep-2018

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 13-Mar-2019.

EU Authorized Representative:
N/A

Signature: _____ **Date** 2019-03-13
Hanne Nielsen, Regulatory Affairs Manager