Natus Medical Incorporated
Natus Medical Denmark ApS
Hørskætten 9
Taastrup
Denmark, 2630

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

CE 0459

Declaration Number: 7-39-02603
Product Name: Otoscan
Product Model Number: Type 1093
Description: 3D Ear Scanner

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 I, by Annex IX, Rule 12
Conformity Assessment Route: Annex VII

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