Natus Manufacturing Limited
IDA Business Park
Gort, Co. Galway
Ireland

European Declaration of Conformity to the Medical Device Regulation, (EU) 2017/745 of the European Parliament, and of the Council of 5 April 2017 on Medical Devices

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CE 2797

CÔNG TY TNHH VIỆT QUANG

PHÓ GIÁM ĐỐC
Đinh Thị Minh Ngọc

Declaration Number:	DOC-066229
Registered Product/Trade Name:	Natus Keypoint
Single Registration Number:	IE-MF-000000799
EMDN code:	N010199 NEUROPHYSIOLOGY DEVICES - OTHER
GMDN code:	46566 Neurophysiologic monitoring system
Product Catalog Number with associated UDI-DI:	See Table 1, below
Intended Purpose:	

Natus Keypoint is intended as an electrophysiological aid to assess diagnosis and prognosis, and to monitor diseases of the central and peripheral nervous system. It can also be used to study functional aspects of nerves and muscles in other fields such as rehabilitation (physical medicine), occupational medicine and sports medicine.

Natus Manufacturing Limited hereby declares that the above medical device(s), which bear the CE Mark, are in conformity with the applicable requirements of the Medical Device Regulation, (EU 2017/745 of the European Parliament, and of the Council of 5 April 2017 on Medical Devices).

Risk Classification/Rule:	Class IIa, Annex VIII Chapter III Rule 10 (MDR 2017/745)
Conformity Assessment Route:	Annex IX, Chapter I & III
Common Specifications Referenced:	N/A

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

Certificate No:	MDR 730073
Issued by:	BSI Group The Netherlands B.V.
Expiry Date:	2027-Dec-19

Additionally: Natus hereby declares conformity under its sole responsibility as Legal Manufacturer and evaluated by the Notified Body listed above, that the product specified on this Declaration of Conformity is in conformity with Commission Delegated Directive 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances. It has been demonstrated that the requirements specified in Annex II of Directive 2015/863 have been met.

Authorized Representative:	**Notified Body:**
N/A- Legal manufacturer is based in EU	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands

Table 1: Natus Keypoint, Catalog Numbers

Category	Product Configuration/Model	Part (Catalog) Number	Basic UDI-DI
Natus Keypoint	Keypoint Focus Module	9033A07-SYS	038283NA00166EN
	Natus Keypoint Focus Notebook System (Laptop)	9033A07N-EN230 9033A07N-GER 9033A07N-FRE 9033A07N-ITA	
	Natus Keypoint Focus Desktop PC System (Desktop)	9033A07D-EN230 9033A07D-GER 9033A07D-FRE 9033A07D-ITA	
	Natus Keypoint G4 (workstation)	9031A07D-EN230 9031A07D-GER 9031A07D-FRE 9031A07D-ITA	
	Keypoint Focus Main Unit	9033G0704	
	Front end box, Keypoint G4	9031G0703	
	Natus 3 channel Amplifier	9033C0731	
	3 channel EMG/EP Amplifier	9031C0732	
	4 channel EMG/EP Amplifier	9031C0742	
	6 channel amplifier box	9031C0762	
	6-ch. EP Amplifier	9031C0771	
	8 channel EMG/EP Amplifier	9031C0782	
	Multi Electrical Stimulator box/amp	9031E0722	
	Natus Stimulus Probe	9031E0172	
	Single Electrical Stimulator box/amp	9031E0712	
	Isolating Transformer, 230V	9031D0411	
	P300 Reaction Time Switch	9033B0332	
	OptiPlex 7000 - Incl Win10 Pro - Labeled - English (MUI)	031637	
	3-Key Foot Switch	9031B0307	

Name: *Sanjay Mehta*

Function: *Director Global Regulatory Affairs, QARA*

Place: *Oakville, Ontario, Canada*

Date of Issue: *23 December 2024*

Signature: Sanjay Mehta