



28th February 2025

CERTIFICATE OF FREE SALE FOR MEDICAL DEVICES

Certificate of Free Sale Number: CFS15659

The Health Products Regulatory Authority (HPRA) hereby certifies the following information for the devices in the attached schedule in accordance with Regulation (EU) 2017/745 on medical devices:

<i>Manufacturer:</i>	Natus Manufacturing Limited IDA Business Park, Gort, Co. Galway, Ireland
<i>Physical site of manufacture:</i>	Natus Manufacturing Limited IDA Business Park, Gort, Co. Galway, Ireland

The manufacturer has declared that the devices are CE marked in accordance with the above legislation and may be marketed and sold in Ireland.

Exportation of these devices is not prohibited.

The granting of this certificate is based on the information available to the HPRA on the date of issue of the certificate. The HPRA does not authorise or approve any devices prior to placing on the market. As the regulatory status of the devices may change, it is important that this certificate is considered in combination with the manufacturer's declaration of conformity and the notified body certificates, where applicable.

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


Cheryl Convey
Medical Devices Department
Health Products Regulatory Authority

An overview of the regulatory framework in Europe can be found on the EU Commission website:
https://ec.europa.eu/health/md_sector/overview_en.



Seen for the authentication of signature/seal
of Cheryl Convey
Health Products Regulatory Authority

Signed Mary Kelleher
Position MD

Date 07/04/2025

This Authentication only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Authentication does not certify the content of the document for which it was issued. To verify an Authentication issued by the Ministry of Foreign Affairs in Ireland, see authentications.dfa.ie

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CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: **Việt Nam**
Country
- Giấy tờ, tài liệu này
This public document
2. do Ông (Bà): **Mary Kelleher** ký
has been signed by
3. với chức danh: **Cán bộ lãnh sự**
acting in the capacity of
4. và con dấu của **Bộ Ngoại giao Ai-len**
bears the stamp of

- được chứng nhận / hợp pháp hóa lãnh sự
Certified
5. tại **London** 6. Ngày **15/4/2025**
at the
7. Cơ quan cấp: **Đại sứ quán Việt Nam tại VQ Anh và CH Ai-len**
by
8. Số: **1522**
Nº

Ký tên và đóng dấu
Signature and seal/stamp
Tham tán
Counsellor



Nguyễn Tuấn Việt

MEDICAL DEVICE SCHEDULE

Device Basic UDI-DI	Product code	Device name	Notified body certificate number	Notified body certificate expiry date
038283NA00166EN	9033A07-SYS	Keypoint Focus Module Kit	MDR 730073	19/12/2027
038283NA00166EN	9033A07N-EN115	Natus Keypoint Focus Notebook System, ENG, 115V	MDR 730073	19/12/2027
038283NA00166EN	9033A07N-EN230	Natus Keypoint Focus Notebook System, ENG, 230V	MDR 730073	19/12/2027
038283NA00166EN	9033A07N-GER	Natus Keypoint Focus Notebook System, GER	MDR 730073	19/12/2027
038283NA00166EN	9033A07N-FRE	Natus Keypoint Focus Notebook System, FRE	MDR 730073	19/12/2027
038283NA00166EN	9033A07N-ITA	Natus Keypoint Focus Notebook System, ITA	MDR 730073	19/12/2027
038283NA00166EN	9033A07D-EN115	Natus Keypoint Focus Desktop System, ENG, 115V	MDR 730073	19/12/2027
038283NA00166EN	9033A07D-EN230	Natus Keypoint Focus Desktop System, ENG, 230V	MDR 730073	19/12/2027
038283NA00166EN	9033A07D-GER	Natus Keypoint Focus Desktop System, GER	MDR 730073	19/12/2027
038283NA00166EN	9033A07D-FRE	Natus Keypoint Focus Desktop System, FRA	MDR 730073	19/12/2027
038283NA00166EN	9033A07D-ITA	Natus Keypoint Focus Desktop System, ITA	MDR 730073	19/12/2027
038283NA00166EN	9031A07D-EN115	Natus Keypoint G4 workstation, EN, 115V	MDR 730073	19/12/2027
038283NA00166EN	9031A07D-EN230	Natus Keypoint G4 workstation, EN-230V	MDR 730073	19/12/2027
038283NA00166EN	9031A07D-GER	Natus Keypoint G4 workstation, GER	MDR 730073	19/12/2027
038283NA00166EN	9031A07D-FRE	Natus Keypoint G4 workstation, FRA	MDR 730073	19/12/2027
038283NA00166EN	9031A07D-ITA	Natus Keypoint G4 workstation, ITA	MDR 730073	19/12/2027