EC CERTIFICATION

EU Quality Assurance System Certificate

Regulation (EU) 2017/745 for Medical Devices, Annex XI Part A

We hereby declare that a conformity assessment based on a production quality assurance system and technical documentation (excluding type-examination) has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620205897

Revision:
00

Initial Certification Date:
24 February 2025

Certificate Decision Date:
24 February 2025

Certificate Issue Date:
24 February 2025

Certificate Expiry Date:
14 March 2029

NeoNavia AB

Stolp-Ekeby 11, 186 95 Vallentuna Sweden

Manufacturer SRN: SE-MF-000045971

Scope:

Biopsy Devices

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00490-001 NeoNavia Base Unit**
Audit Report Reference	**Stage 1 audit ACTY-2023-146970**
	Stage 2 audit ACTY-2023-146971
	Special audit ACTY-2025-301482
Change Notice Reference	

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620205897	24 February 2025	Initial Certificate

PRODUCT LIST FOR CERTIFICATE

Issued to: NeoNavia AB

Certificate number: 28620205897

Certificate valid from: 2025-02-24

Product List Issue Date:
24 February 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Biopsy Devices			
Basic UDI-DI: 735008194NEONAVIAPROBED2			
REF#2102 - NeoNavia VacuPulse Probe	Class IIa A01020199		2025-02-24
REF#2103 - NeoNavia CorePulse Probe	Class IIa A01020199		2025-02-24
REF#2104 - NeoNavia FlexiPulse Probe	Class IIa A01020199		2025-02-24
Basic UDI-DI: 735008194NEONAVIAREUSEDE			
REF#1102 - NeoNavia Base Unit	Class IIa A01020199		2025-02-24
REF#1103 - NeoNavia Driver	Class IIa A01020199		2025-02-24

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.