EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation 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:
28620194069

Revision:
00

Initial Certification Date:
17 October 2024

Certificate Decision Date:
17 October 2024

Certificate Issue Date:
17 October 2024

Certificate Expiry Date:
12 April 2029

ClaroNav Inc.

1140 Sheppard Ave W, Unit 10, Toronto, Ontario M3K 2A2 Canada

Manufacturer SRN: CA-MF-000028837

Authorised Representative Name

Emergo Europe B.V.

Westervoortsedijk, 60 6827 AT Arnhem, Netherlands

Scope:

- Surgical navigation system

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
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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	**TD00275-001 ClaroNav Inc. Navident EVO Cart**
Audit Report Reference	**Stage 1 audit ACTY-2023-097528**
	Stage 2 audit ACTY-2023-097529

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620194069	17 October 2024	Initial certificate

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PRODUCT LIST FOR CERTIFICATE

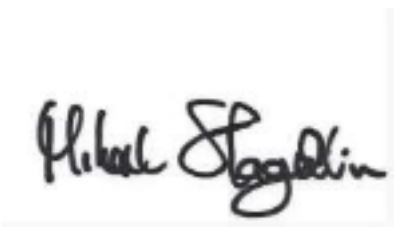
Issued to: ClaroNav Inc.

Certificate number: 28620194069

Certificate valid from: 2024-10-17

Product List Issue Date:
17 October 2024

Product	Classification and EMDN	Intended use[1]	Date Added
Surgical navigation system			
Basic UDI-DI: 7540209955-ND-NDUL			
955-ND-ND-201 - Navident EVO Cart	Class IIa Z12011401		2024-10-17
955-ND-ND-202 - Navident EVO Mount	Class IIa Z12011401		2024-10-17



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