EC CERTIFICATION

EU 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.

Luméd Inc.

Bureau 400 6 rue Wellington SudSherbrooke,, Quebec (Québec), J1H 5C7, Canada

Manufacturer SRN: CA-MF-000042277

Authorised Representative Name
bioMérieux S.A.,

Chemin de l'Orme 376,69280 Marcy-L'Étoile France.

Scope:

- Clinical decision support software

Certificate Number:
28620199074

Revision:
01

Initial Certification Date:
25 November 2024

Certificate Decision Date:
29 January 2025

Certificate Issue Date:
29 January 2025

Certificate Expiry Date:
31 January 2029

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	**TD00044-001 APSS**
Audit Report Reference	**Stage 1 audit ACTY-2023-121493** **Stage 2 audit ACTY-2023-121494**
Change Notice	**CN00044-06**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

Certificate Number:
28620199074

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620199074	25 November 2024	Initial Certificate
28620199074	29 January 2025	Change to EU AR

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PRODUCT LIST FOR CERTIFICATE

Issued to: Luméd Inc.

Certificate number: 28620199074-01

Certificate valid from: 2025-01-29

Product List Issue Date:
29 January 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Software			
Basic UDI-DI: 75401534001MX			
UDI-DI: (01)17540153400000 - APSS V92	Class IIa		2024-11-25

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