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, restricted to the aspects relating to the conformity of the devices with sterility and reusability requirements, 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.

Elliquence, LLC

2455 Grand Avenue, Baldwin, New York 11510, United States

Manufacturer SRN: US-MF-000024036

Authorised Representative:
Emergo Europe BV
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

Scope:
Reusability and sterility aspects of Class Ir,s devices as detailed in attached product list

Certificate Number:
28620156608

Revision:
01

Initial Certification Date:
18 September 2023

Certificate Decision Date:
02 March 2026

Certificate Issue Date:
02 March 2026

Certificate Expiry Date:
19 November 2027

Mikael Hagelin
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

Last Audit report reference	
Change notice reference	**CN00204-009**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620156608	18 September 2023	Initial certificate
28620156608-01	02 March 2026	Scope (device) expansion

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