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.

Elliquence, LLC

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

Manufacturer SRN: US-MF-000024036

Authorised Representative Name

Emergo Europe BV

Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

Scope:

- Endoscopes
- Electrosurgical generators
- Electrosurgical instruments

Certificate Number:
28620156609

Revision:
01

Initial Certification Date:
18 September 2023

Certificate Decision Date:
14 August 2025

Certificate Issue Date:
14 August 2025

Certificate Expiry Date:
19 November 2027

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
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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.