EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 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 EU Regulation 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:
28620121250

Revision:
02

Initial Certification Date:
19 January 2022

Certificate Decision Date:
27 September 2023

Certificate Issue Date:
27 September 2023

Certificate Expiry Date:
18 January 2027

H&A Mui Enterprises Inc (Mui Scientific)

Unit 34, 145 Traders Blvd. E, Mississauga, Ontario, L4Z 3L3, Canada

Manufacturer SRN: CA-MF-000016542

Authorised Representative Name
Advena Ltd
Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR, 4013, Malta

Scope:

- Non sterile manometric catheters (in 3 different category), class IIa for gastrointestinal motility diagnosis
- Barostat bag pump with barostat non sterile catheters, class IIa for the diagnosis of anorectal disorders

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	**CN00015-02**
Audit Report Reference	**CN00015-02**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620121250	19 Jan 2022	Change of scope
28620121250-01	14 June 2023	Change of scope

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