# 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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# MDR – Decision Report

| | |
|---|---|
| Certificate No: | 28620121250-02 |
| Date: | 27 September 2023 |
| Handled by: | Caroline Åman |
| E-mail: | IMNB@intertek.com |

**H&A Mui Enterprises Inc (Mui Scientific)**
Attn: Fatemeh Rahimi
Unit 34, 145 Traders Blvd. E,
Mississauga, Ontario, L4Z 3L3,
Canada

| | |
|---|---|
| **Purpose** | Assessment to issue a new certificate with new scope.<br>- Introducers, class IIa to aid catheter intubation has been removed from the scope.<br>Decision was made according to the Medical Device Regulation 2017/745, Annex IX. |
| **Activity** | Products has been removed from client´s product list and handled in Change Notice CN00015-02 |
| **Scope of assessment** | - Non sterile manometric catheters (in 3 different category), class IIa for gastrointestinal motility diagnosis<br>- Barostat bag pump with barostat non sterile catheters, class IIa for the diagnosis of anorectal disorders<br>Class IIa |
| **Result** | The removal of product has been accepted and the scope can be updated. |
| **Certificate Valid from** | 27 September 2023 |
| **Conclusions/Decisio** | Referring to the above a Certificate of Conformance with the Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”. |
| **Follow-up** | Follow-up assessments are going to be performed once per year |
| **Appeals** | Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden. |

**Others**

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

**Intertek Medical Notified Body AB**
Notified Body MDR

Brian Mather
Certification Authority

# PRODUCT LIST FOR CERTIFICATE

**Issued to:** H&A Mui Enterprises Inc (Mui Scientific)

**Certificate number:** 28620121250-02

**Certificate valid from:** 2023-09-27

**Product List Issue Date:**
27 September 2023

| Product | Classification and EMDN | Intended use[1] | Date Added |
|---|---|---|---|
| **Devices for investigation of the gastroinstinal system** | | | |
| ***Basic UDI-DI: 0678467DENTSLEEVEE9*** | | | |
| APDSH: Antropyloroduodenal w/ side holes - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| ASH: Anorectal w/ side holes - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| ASS: Anorectal w/side holes & sleeve - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CE1: Non-sleeve esophageal - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CE2:w/ Sleeve esophageal - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CE4: Customized Esophageal - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CE5: Customized Esophageal w/ sleeve - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CPE1:Non-sleeve pediatric esophageal - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CPE2:w/ Sleeve pediatric esophageal - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CPR1: Non-sleeve pediatric anorectal - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CPR2: w/ Sleeve pediatric anorectal - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CR1: Non-sleeve anorectal - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CR2: w/ Sleeve anorectal - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CR4: Customized Anorectal - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| CR5: Customized Anorectal w/ sleeve - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| LOSS: Lower Esophageal w/ Side holes & Sleeve - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |

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

| Product | Classification and EMDN | Intended use[1] | Date Added |
|---|---|---|---|
| OSH: Esophageal w/ side holes - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| PYS: Pyloric w/ sleeve - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| SISH: Small Intestines w/ side holes - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| UOSS: Upper Esophageal w/ Side holes & Sleeve - Dentsleeve Reusable Catheter | Class IIa | | 2022-01-19 |
| ***Basic UDI-DI: 0678467PVCRU7N*** | | | |
| C7: Customized Reusable - PVC Reusable Catheter | Class IIa | | 2022-01-19 |
| CB-CE: Barostat Esaphageal - PVC Reusable Catheter | Class IIa | | 2022-01-19 |
| CB-CG: Barostat Gastric - PVC Reusable Catheter | Class IIa | | 2022-01-19 |
| CB-CR: Barostat Rectal - PVC Reusable Catheter | Class IIa | | 2022-01-19 |
| E:Esophageal - PVC Reusable Catheter | Class IIa | | 2022-01-19 |
| PE: Pediatric Espophageal - PVC Reusable Catheter | Class IIa | | 2022-01-19 |
| PH7: Acid Loading - PVC Reusable Catheter | Class IIa | | 2022-01-19 |
| PR: Pediatric Rectal - PVC Reusable Catheter | Class IIa | | 2022-01-19 |
| R: Rectal - PVC Reusable Catheter | Class IIa | | 2022-01-19 |
| S: Small Bowell - PVC Reusable Catheter | Class IIa | | 2022-01-19 |
| ***Basic UDI-DI: 0678467PVCSU7R*** | | | |
| S7: Customized single Use - PVC Single Use Catheter | Class IIa | | 2022-01-19 |
| S7-CB-E: Single-Use Barostat Esophageal - PVC Single Use Catheter | Class IIa | | 2022-01-19 |
| S7-CB-G: Single-Use Barostat Gastric - PVC Single Use Catheter | Class IIa | | 2022-01-19 |
| S7-CB-R: Single-Use Barostat Rectal - PVC Single Use Catheter | Class IIa | | 2022-01-19 |
| SE: Single-Use Esophageal - PVC Single Use Catheter | Class IIa | | 2022-01-19 |
| SPE:Single-Use Pediatric Esophageal - PVC Single Use Catheter | Class IIa | | 2022-01-19 |
| SPRB:Single-Use Pediatric Rectal w/ Balloon - PVC Single Use Catheter | Class IIa | | 2022-01-19 |
| SR:Single-Use Rectal - PVC Single Use Catheter | Class IIa | | 2022-01-19 |

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

*Certificate number:* 28620121250-02
*Product list issue date:* 27 September 2023

| Product | Classification and EMDN | Intended use[1] | Date Added |
|---|---|---|---|
| ***Basic UDI-DI: 0678467RBBGD*** | | | |
| P1-RBB-1 - RBB Pump | Class IIa | | 2022-01-19 |

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