UKCA CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of UK Statutory Instrument 2002 No. 618, as amended, to which the undersigned is subjected.

We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organisation to use the UKCA 8532 marking on those products listed below.

H&A Mui Enterprises Inc (Mui Scientific)

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

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 diagnosis of anorectal disorders

For further identification of the products covered, see the attached product list/product schedule

Certificate Number:
85320226606
Revision
00
Initial Certification Date:
26 September 2025
Date of Certification Decision:
26 September 2025
Certificate Valid Date:
26 September 2025
Certificate Expiry Date:
18 January 2027

Sharmila Gardner
Head of UK Approved Body
Intertek Medical Notified Body UK Ltd
Academy Place, 1-9 Brook Street
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The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the UK Approved Body.

Intertek Medical Notified Body UK Ltd is a UK Approved Body according to UK SI 2002 No. 618 on medical devices, with identification number 8532.

PRODUCT LIST FOR CERTIFICATE

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

Certificate number: 85320226606

Certificate valid from: 2025-09-26

Product List Issue Date:
26 September 2025

Product	Classification and GMDN	Intended use[1]	Date Added
Devices for investigation of the gastroinstinal system			
Product Group: Catheters and overtubes			
APDSH: Antropyloroduodenal w/ side holes - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
ASH: Anorectal w/ side holes - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
ASS: Anorectal w/side holes & sleeve - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
C7: Customized Reusable - PVC Reusable Catheter	Class IIa 17745		2025-09-26
CB-CE: Barostat Esophageal - PVC Reusable Catheter	Class IIa 17745		2025-09-26
CB-CG: Barostat Gastric - PVC Reusable Catheter	Class IIa 17745		2025-09-26
CB-CR: Barostat Rectal - PVC Reusable Catheter	Class IIa 17745		2025-09-26
CE1: Non-sleeve esophageal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CE2:w/ Sleeve Esophageal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CE4: Customized Esophageal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CE5: Customized Esophageal w/ sleeve - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CNE2:w/ Sleeve Neonate Esophageal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CPE1:Non-sleeve Pediatric Esophageal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CPE2:w/ Sleeve Pediatric Esophageal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CPR1: Non-sleeve Pediatric Anorectal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CPR2: w/ Sleeve pediatric anorectal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CR1: Non-sleeve anorectal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26

1 The intended use is only included for Class IIb and Class III devices.

Product	Classification and GMDN	Intended use[1]	Date Added
CR2: w/ Sleeve anorectal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CR4: Customized Anorectal - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
CR5: Customized Anorectal w/ sleeve - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
E:Esophageal - PVC Reusable Catheter	Class IIa 17745		2025-09-26
LOSS: Lower Esophageal w/ Side holes & Sleeve - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
OSH: Esophageal w/ side holes - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
PE: Pediatric Espophageal - PVC Reusable Catheter	Class IIa 17745		2025-09-26
PH7: Acid Loading - PVC Reusable Catheter	Class IIa 17745		2025-09-26
PR: Pediatric Rectal - PVC Reusable Catheter	Class IIa 17745		2025-09-26
PYS: Pyloric w/ sleeve - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
R: Rectal - PVC Reusable Catheter	Class IIa 17745		2025-09-26
S: Small Bowell - PVC Reusable Catheter	Class IIa 17745		2025-09-26
S7: Customized single Use - PVC Single Use Catheter	Class IIa 17745		2025-09-26
S7-CB-E: Single-Use Barostat Esophageal - PVC Single Use Catheter	Class IIa 17745		2025-09-26
S7-CB-G: Single-Use Barostat Gastric - PVC Single Use Catheter	Class IIa 17745		2025-09-26
S7-CB-R: Single-Use Barostat Rectal - PVC Single Use Catheter	Class IIa 17745		2025-09-26
SE: Single-Use Esophageal - PVC Single Use Catheter	Class IIa 17745		2025-09-26
SISH: Small Intestines w/ side holes - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
SPE:Single-Use Pediatric Esophageal - PVC Single Use Catheter	Class IIa 17745		2025-09-26
SPRB:Single-Use Pediatric Rectal w/ Balloon - PVC Single Use Catheter	Class IIa 17745		2025-09-26
SR:Single-Use Rectal - PVC Single Use Catheter	Class IIa 17745		2025-09-26
UOSS: Upper Esophageal w/ Side holes & Sleeve - Dentsleeve Reusable Catheter	Class IIa 17745		2025-09-26
Product Group: Rapid Barostat Bag Pump			

[1]The intended use is only included for class IIb devices and class III devices.

Certificate number: 85320226606
Product list issue date: 26 September 2025

Product	Classification and GMDN	Intended use[1]	Date Added
P1-RBB-1 - RBB Pump	Class IIa 45569		2025-09-26

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[1]The intended use is only included for class IIb devices and Class II devices.

Certificate number: 85320226606
Product list issue date: 26 September 2025