

EC DECLARATION OF CONFORMITY FOR MUCUS EXTRACTORS AND SPECIMEN TRAPS

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
concerning Medical Devices

Legal Name:	IVOR SHAW LIMITED
Trade Name:	Pennine Healthcare
Manufacturer SRN:	GB-MF-000004160
Business Address:	300 City Gate London Road Derby DE24 8WY United Kingdom
EU Authorised Representative (AR):	Advena Ltd. Tower Business Centre, 2 nd Floor, Tower Street, Swatar, BKR 4013, Malta
EU AR SRN:	MT-AR-000000234
Product Name:	Mucus Extractors and Mucus Specimen Traps
Product Codes:	Refer to Appendix 2
Device Classification:	Class Is, Rule 1 and 5 (Indent 1) according to Annex VIII, MDR (EU) 2017/745
Common Specifications:	N/A
Intended use:	Pennine's Mucus Extractors and Specimen Traps are a single use, covered plastic receptacle and associated tubing, containing no additives intended to be used for the aspiration, and/or collection of mucus/sputum specimens required for further examination. To be used on all patient populations, by clinician or suitably trained person, in a clinical setting.
Basic UDI-DI:	UDI-DI - 5033241MUCUSEXTRACTORSR8
Notified Body:	BSI Group The Netherlands B.V
Notified Body Certificate Number:	2797
MDR Certificate Number:	766979
Conformity Assessment Route:	Annex IX Chapters I and III of EU MDR 2017/745

GMDN: **62853:** Oropharyngeal secretion specimen suction kit. A collection of devices intended exclusively for professional use to obtain by suction a mucus/sputum specimen from the oropharynx of a neonate for microbiological examination; it might in addition be used to clear mucus from the oropharynx to assist respiration. It consists of a catheter/tube intended to be inserted orally, a piece of suction tubing intended to be attached to an appropriate pump (not included), an empty specimen collection container, and appropriate adapters/lids. This is a single-use device

EMDN: **R05010301:** Respiratory and anaesthesia devices. Single chamber mucous membrane aspirators.

We hereby declare that the medical devices listed above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration of conformity is issued under the sole responsibility of Ivor Shaw Limited trading as Pennine Healthcare.

Signed By:

Date: 29/July/2022

M. Arun

Name: **Arun Mahendran**

Position: **Head of Regulatory Affairs**

Place: Derby, United Kingdom

On behalf of IVOR SHAW LTD t/a Pennine Healthcare, Derby, United Kingdom.

Appendix 1 Applicable Standards:

Standard/Document Name	Description
(EU) 2017/745	Medical Device Regulation
SI 2002 No 618, as amended	(UK) Medical Devices Regulations
EN ISO 13485:2016	Medical Devices–Quality Management Systems–Requirements for regulatory purpose
EN ISO 14971:2019	Medical Devices–Application of Risk Management to medical device
EN ISO 10993-1:2018	Biological evaluation of medical devices–Part 1: Evaluation and Testing within a risk management process
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments–Part 1: Classification of air cleanliness by particle contamination
EN ISO 20417:2021	Information supplied by the manufacturer of medical device
EN ISO 15223-1:2021	Medical Devices–Symbols to be used with medical device labels, labelling and information to be supplied–Part 1: General Requirements
EN ISO 62366-1:2015	Medical Devices–Part 1: Application of usability engineering to medical devices
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems.
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
EN 6256:2021	Packaging for sterile medical devices
EN ISO 20696:2018	Sterile Urethral Catheters for Single Use

Appendix 2 Product List:

Product Code	Description	UDI-DI
ME-8108	Mucus Extractor 20ml, 8fg x 33cm tube, with patient label and spare screw cap	Unit: 05033241021843 Outer: 05033241110646
ME-8110	Mucus Extractor 20ml, 10fg x 33cm tube, with patient label and spare screw cap	Unit: 05033241021850 Outer: 05033241110653
ME-8112	Mucus Extractor 20ml, 12fg x 33cm tube, with patient label and spare screw cap	Unit: 05033241021867 Outer: 05033241110660
ME-8114	Mucus Extractor 20ml, 14fg x 33cm tube, with patient label and spare screw cap	Unit: 05033241021874 Outer: 05033241110677
ME-9108	Mucus Extractor 20ml, 8fg x 33cm tube, VC, with patient label and spare screw cap	Unit: 05033241021881 Outer: 05033241110684
ME-9110	Mucus Extractor 20ml, 10fg x 33cm tube, VC, with patient label and spare screw cap	Unit: 05033241021898 Outer: 05033241110691
ME-9112	Mucus Extractor 20ml, 12fg x 33cm tube, VC, with patient label and spare screw cap	Unit: 05033241021904 Outer: 05033241110707
ME-9114	Mucus Extractor 20ml, 14fg x 33cm tube, VC, with patient label and spare screw cap	Unit: 05033241021911 Outer: 05033241110714
ME-9214	Mucus Extractor 14fg, 500mm, 20ml, VC	Unit: 05033241021928 Outer: 05033241000794
MST-3000	Mucus Specimen Trap 30ml, 20fg x 14cm, with patient label and spare screw cap	Unit: 05033241022116 Outer: 05033241110035
MST-3070	Mucus Specimen Trap 30ml, 20fg x 6cm, with patient label and spare screw cap	Unit: 05033241022147 Outer: 05033241110042
MST-3180	Mucus Specimen Trap 30ml, 18fg x 29cm, with patient label and spare screw cap	Unit: 05033241022178 Outer: 05033241110059
MST-4000	Mucus specimen trap 70ml Screw cap and spare screw cap	Unit: 05033241022185 Outer: 05033241110394
MST-4000/S	Mucus specimen trap 70ml Screw cap and spare screw cap	Unit: 05033241022215 Outer: 05033241110486
MST-5000	Mucus specimen trap 20ml 16fg tube VC2 - screw cap & spare	Unit: 05033241022222 Outer: 05033241110417
MST-7000	Mucus specimen trap 14fg with male connector	Unit: 05033241022239 Outer: 05033241110479