

EC DECLARATION OF CONFORMITY FOR STERILE SUCTION CONNECTING TUBES

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:	Sterile Suction Connecting Tubes
Product Codes:	Refer to Appendix 2.
Device Classification:	Class Is, Rule 1 according to Annex VIII, MDR (EU) 2017/745
Common Specifications:	N/A
Intended use:	Pennine's Sterile Connecting Tubes are a length of flexible single use, non-invasive PVC tubing, intended to interface between suction source and suction devices for use in a medical/surgical procedure removing fluids, gasses, and debris. They are supplied and intended to be used sterile by clinicians or trained homecare user, in clinical, homecare and emergency settings.
Basic UDI-DI:	UDI-DI - 5033241CONNECTINGTUBESJQ
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:	16779 – Suction/Irrigation Tubing, single-use. A length of flexible non-invasive tube, typically made of synthetic polymer material(s), intended to interface between suction and/or irrigation devices (e.g., catheters, pumps, collection

bottles) during a medical/surgical procedure. The tubing may be provided in rolls from which required lengths are cut or may be provided in predetermined lengths with connectors; it does not include additional associated items such as a clamp, spike, or bag (i.e., not a tubing set). This is a single-use device.

EMDN: A060102 - Devices for administration, withdrawal and collection - Surgical drainage connection medical tubes

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: *S. Watkins*

Date: 16th May 2024

Name: **Samantha Watkins**

Position: **Regulatory Affairs Manager**

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 10993-7:2008 / AMD1:2019	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants
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 10079-3:2014	Medical Suction Equipment Part 3: Suction equipment powered from a vacuum or positive pressure gas source
EN ISO 11607-1:2019	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems.
EN ISO 11607-2:2019	Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly process.
EN ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

Appendix 2 Product List:

Product Code	Description	UDI-DI
CT-4511	Suction Connecting Tube Link 5mm x 1.8m M/F	Unit: 05033241011127 Outer: 05033241130293
CT-4513	Suction Connecting Tube Link 5mm x 2.7m F/F	Unit: 05033241011134 Outer: 05033241130309
CT-4541	Suction Connecting Tube Link 5mm x 2.7m M/F	Unit: 05033241011172 Outer: 05033241130989
CT-4543	Suction Connecting Tube Link 5mm x 2.7m F/F	Unit: 05033241011189 Outer: 05033241130996
CT-4711	Suction Connecting Tube Link 7mm x 1.8m F/M	Unit: 05033241011523 Outer: 05033241130613
CT-4713	Suction Connecting Tube Link 7mm x 1.8m F/F	Unit: 05033241011547 Outer: 05033241130620
CT-4741	Suction Connecting Tube Link 7mm x 2.7m F/M	Unit: 05033241011691 Outer: 05033241131412
CT-4743	Suction Connecting Tube Link 7mm x 2.7m F/F	Unit: 05033241011721 Outer: 05033241131429
CT-4783	Suction Connecting Tube Link 7mm x 3.7m F/F	Unit: 05033241011837 Outer: 05033241130033

CT-4011	Suction Connecting Tube 6mm x 1.8m M/F	Unit: 05033241009650 Outer: 05033241130347
CT-4012	Suction Connecting Tube 6mm x 1.8m F/F	Unit: 05033241009674 Outer: 05033241130552
CT-4014	Suction Connecting Tube 6mm x 1.8m F/F/M	Unit: 05033241009735 Outer: 05033241130583
CT-4014/VC	Suction Connecting Tube 6mm x 1.8m F/F/M VC	Unit: 05033241009766 Outer: 05033241130590
CT-4015	Suction Connecting Tube 6mm x 1.8m F/VC	Unit: 05033241009773 Outer: 05033241000695
CT-4020	Suction Connecting Tube 6mm x 2mt F/Flush cut end	Unit: 05033241009780 Outer: 05033241130705
CT-4021	Suction Connecting Tube 6mm x 2m F/M	Unit: 05033241009841 Outer: 05033241136684
CT-4021/VC	Suction Connecting Tube 6mm x 2m F/F VC	Unit: 05033241009919 Outer: 05033241130743
CT-4022	Suction Connecting Tube 6mm x 2m F/F	Unit: 05033241009988 Outer: 05033241136554
CT-4022/50	Suction Connecting Tube 6mm x 2m F/F	Unit: 05033241009995 Outer: 05033241136844
CT-4022/E	Suction Connecting Tube 6mm x 2m F/F	Unit: 05033241010021 Outer: 05033241131573
CT-4024	Suction Connecting Tube 6mm x 2m F/F/M	Unit: 05033241010168 Outer: 05033241130842
CT-4024/AC	Suction Connecting Tube 6mm x 2m with AC Connector	Unit: 05033241010175 Outer: 05033241133157
CT-4024/VC	Suction Connecting Tube 6mm x 2m F/F/M VC	Unit: 05033241010212 Outer: 05033241130859
CT-4025	Suction Connecting Tube 6mm x 2m F/VC	Unit: 05033241010243 Outer: 05033241130873
CT-4028	Suction Connecting Tube 6mm x 2m F/Straight probe end	Unit: 05033241010342 Outer: 05033241131634
CT-4030	Suction Connecting Tube 6mm x 3m F/Flush cut end	Unit: 05033241010359 Outer: 05033241136707
CT-4031/G	Suction Connecting Tube 6mm x 3m M/F	Unit: 05033241010397 Outer: 05033241130064
CT-4031/W	Suction Connecting Tube 6mm x 3m M/F	Unit: 05033241010403 Outer: 05033241130071
CT-4032	Suction Connecting Tube 6mm x 3m F/F	Unit: 05033241010434 Outer: 05033241136578
CT-4032/50	Suction Connecting Tube 6mm x 3m F/F	Unit: 05033241010441 Outer: 05033241136622
CT-4032/WW	Suction Connecting Tube 6mm x 3m F/F	Unit: 05033241010564 Outer: 05033241130248
CT-4034	Suction Connecting Tube 6mm x 3m F/F/M	Unit: 05033241010595 Outer: 05033241130354 Pallet: 05033241100067
CT-4034/50	Suction Connecting Tube 6mm x 3m F/F/M	Unit: 05033241010601 Outer: 05033241134048
CT-4034/AC	Suction Connecting Tube 6mm x 3m F/F/M with AC connector	Unit: 05033241010625 Outer: 05033241132778
CT-4034/VC	Suction Connecting Tube 6mm x 3m F/F/M VC	Unit: 05033241012841 Outer: 05033241130361
CT-4034/W	Suction Connecting Tube 6mm x 3m F/F/M	Unit: 05033241012872 Outer: 05033241133621
CT-4038	Suction Connecting Tube 6mm x 3m F/Straight probe end	Unit: 05033241012896 Outer: 05033241132358

CT-4042	Suction Connecting Tube 6mm x 2.7m F/F	Unit: 05033241012957 Outer: 05033241131269
CT-4042/SD	Suction Connecting Tube 6mm x 2.7m F/F	Unit: 05033241012971 Outer: 05033241131283
CT-4044	Suction Connecting Tube 6mm x 2.7m F/F/M	Unit: 05033241013015 Outer: 05033241131306
CT-4044/VC	Suction Connecting Tube 6mm x 2.7m F/F/M VC	Unit: 05033241013039 Outer: 05033241131313
CT-4062	Suction Connecting Tube 6mm x 6m F/F	Unit: 05033241013084 Outer: 05033241136615
CT-4062/WG	Suction Connecting Tube 6mm x 6m F/F	Unit: 05033241013121 Outer: 05033241130484
CT-4064	Suction Connecting Tube 6mm x 6m F/F/M	Unit: 05033241013176 Outer: 05033241131719
CT-4072	Suction Connecting Tube 6mm x 3.5m F/F	Unit: 05033241013220 Outer: 05033241131191
CT-4072/40	Suction Connecting Tube 6mm x 3.5m F/F	Unit: 05033241013237 Outer: 05033241136851
CT-4074	Suction Connecting Tube 6mm x 3.5m F/F/M	Unit: 05033241013282 Outer: 05033241131214
CT-4082	Suction Connecting Tube 6mm x 1m F/F	Unit: 05033241013350 Outer: 05033241130101
CT-4092	Suction Connecting Tube 6mm x 4m F/F	Unit: 05033241013398 Outer: 05033241130392
CT-4094	Suction Connecting Tube 6mm x 4m F/F/M	Unit: 05033241013442 Outer: 05033241130415
CT-4152	Suction Connecting Tube 6mm x 1.5m F/F	Unit: 05033241010663 Outer: 05033241133119
CT-4311	Suction Connecting Tube 5mm x 1.8m M/F	Unit: 05033241010717 Outer: 05033241130149
CT-4312	Suction Connecting Tube 5mm x 1.8m F/F	Unit: 05033241010724 Outer: 05033241130156
CT-4314	Suction Connecting Tube 5mm x 1.8m F/F/M	Unit: 05033241010779 Outer: 05033241130163
CT-4314/VC	Suction Connecting Tube 5mm x 1.8m F/F/M VC	Unit: 05033241010793 Outer: 05033241130170
CT-4324/VC	Suction Connecting Tube 5mm x 2m F/F/M	Unit: 05033241010854 Outer: 05033241132143
CT-4332	Suction Connecting Tube 5mm x 3m F/F	Unit: 05033241010861 Outer: 05033241132952
CT-4332/ES	Suction Connecting Tube 5mm x 3m F/F (Single Wrap)	Unit: 05033241010892 Outer: 05033241133713
CT-4334	Suction Connecting Tube 5mm x 3m F/F/M	Unit: 05033241010915 Outer: 05033241134178
CT-4334/VC	Suction Connecting Tube 5mm x 3m F/F/M VC	Unit: 05033241010939 Outer: 05033241132150
CT-4335	Suction Connecting Tube 5mm x 3m F/F	Unit: 05033241055367 Outer: 05033241055350
CT-4354/VC	Suction Connecting Tube 5mm x 1.5m F/F/M VC	Unit: 05033241010953 Outer: 05033241130132
CT-4362	Suction Connecting Tube 5mm x 2.7m F/F	Unit: 05033241010977 Outer: 05033241130934
CT-4364	Suction Connecting Tube 5mm x 2.7m F/F/M	Unit: 05033241011004 Outer: 05033241130941
CT-4372	Suction Connecting Tube 5mm x 3.5m F/F	Unit: 05033241011035 Outer: 05033241131146

CT-4374	Suction Connecting Tube 5mm x 3.5m F/F/M	Unit: 05033241011066 Outer: 05033241131153
CT-4394/VC	Suction Connecting Tube 5mm x 2.7m F/F/M VC	Unit: 05033241011110 Outer: 05033241130958
CT-4622	Suction Connecting Tube 8mm x 2m F/F	Unit: 05033241011233 Outer: 05033241130491
CT-4624	Suction Connecting Tube 8mm x 2m F/F/M	Unit: 05033241011264 Outer: 05033241130514
CT-4630	Suction Connecting Tube 8mm x 3m F/Flush cut end	Unit: 05033241011288 Outer: 05033241136424
CT-4632	Suction Connecting Tube 8mm x 3m F/F	Unit: 05033241011301 Outer: 05033241130538
CT-4634	Suction Connecting Tube 8mm x 3m F/F/M	Unit: 05033241011356 Outer: 05033241131023
CT-4634/VC	Suction Connecting Tube 8mm x 3m F/F/M VC	Unit: 05033241011363 Outer: 05033241131030
CT-4642	Suction Connecting Tube 8mm x 4m F/F	Unit: 05033241011370 Outer: 05033241131054
CT-4672	Suction Connecting Tube 8mm x 3.5m F/F	Unit: 05033241011455 Outer: 05033241131764
CT-4674	Suction Connecting Tube 8mm x 3.5m F/F/M	Unit: 05033241011479 Outer: 05033241131047
CT-4822	Suction Connecting Tube 6mm x 2.4m F/F Guys	Unit: 05033241011851 Outer: 05033241130903
CTS-4022	Suction Connecting Tube Soft 6mm x 2m F/F	Unit: 05033241012025 Outer: 05033241136677
CTS-4025	Suction Connecting Tube Soft 6mm x 2m F/M VC	Unit: 05033241012124 Outer: 05033241136660
CTS-4026	Connecting Tubing 6mm, 2.0m Length Female/Male Luer Lock	Unit: 05033241054049 Outer: 05033241054018
CTS-4032	Suction Connecting Tube Soft 6mm x 3m F/F	Unit: 05033241012155 Outer: 05033241136639
CTS-4032/WG	Suction Connecting Tube Soft 6mm x 6mm x 3m F/F	Unit: 05033241012216 Outer: 05033241131139
CTS-4062	Suction Connecting Tube Soft 6mm x 6m F/F	Unit: 05033241037967 Outer: 05033241037950
CTS-4072	Suction Connecting Tube Soft 6mm x 3.5m F/F	Unit: 05033241012322 Outer: 05033241136592
CTS-4092	Suction Connecting Tube Soft 6mm x 4m F/F	Unit: 05033241012391 Outer: 05033241132259
CTS-4328	Suction Connecting Tube Soft 5mm x 2m F/Soft Tube End	Unit: 05033241064291 Outer: 05033241064307
CTS-4332	Suction Connecting Tube Soft 5mm x 3m F/F	Unit: 05033241012445 Outer: 05033241131825
CTS-4338	Suction Connecting Tube Soft 5mm x 3m F/Soft Tube End	Unit: 05033241064055 Outer: 05033241064062
CTS-4378	Suction Connecting Tube Soft 5mm x 3.5m F/Soft Tube End	Unit: 05033241064079 Outer: 05033241064086
CTS-4640/R	Suction Connecting Tube Soft 8mm x 4m F/Flush cut end	Unit: 05033241012506 Outer: 05033241132235
CT-4714/VC	Suction Connecting Tube Flexi Rib VC 7mm x 1.8m F/F/M	Unit: 05033241011561 Outer: 05033241134185
CT-4722	Suction Connecting Tube Flexi Rib 7mm x 2m F/F	Unit: 05033241011585 Outer: 05033241134208
CT-4732	Suction Connecting Tube Flexi Rib 7mm x 3m F/F	Unit: 05033241011646 Outer: 05033241134215

CT-4734	Suction Connecting Tube Flexi Rib 7mm x 3m F/F/M	Unit: 05033241011660 Outer: 05033241134147
CT-4741/VC	Suction Connecting Tube Flexi Rib VC 7mm x 2.5m F/F/M	Unit: 05033241011707 Outer: 05033241134192
CT-4772	Suction Connecting Tube Flexi Rib 7mm x 3.5m F/F	Unit: 05033241011769 Outer: 05033241134222
CT-4774	Suction Connecting Tube Flexi Rib 7mm x 3.5m F/F/M	Unit: 05033241011783 Outer: 05033241000190
CT-4782	Suction Connecting Tube Flexi Rib 7mm x 3.7m F/F	Unit: 05033241011813 Outer: 05033241000510
CT-4922	Suction Connecting Tube Flexi Rib 6mm x 2m F/F	Unit: 05033241011875 Outer: 05033241133812
CT-4924	Suction Connecting Tube Flexi Rib 6mm x 2m F/F/M	Unit: 05033241011899 Outer: 05033241134406
CT-4932	Suction Connecting Tube Flexi Rib 6mm x 3m F/F	Unit: 05033241011905 Outer: 05033241133829
CT-4934	Suction Connecting Tube Flexi Rib 6mm x 3m F/F/M	Unit: 05033241011929 Outer: 05033241134390
CT-4972	Suction Connecting Tube Flexi Rib 6mm x 3.5m F/F	Unit: 05033241011950 Outer: 05033241133836
CT-4978	Suction Connecting Tube Flexi Rib 6mm x 3.5m F/Straight probe end	Unit: 05033241046303 Outer: 05033241046297
IM-48422	Suction Connecting Tube Set x2 1.0m, 6mm, F/F/M & 2.0m, 6mm, F/F	Unit: 05033241017334 Outer: 05033241131108
DP-501	Straight Rigid Connector	Unit: 05033241013534 Outer: 05033241141336
VCU-2	Vacuum control unit	Unit: 05033241034119 Outer: 05033241132105
AT-4000	Suction/ Aspiration Tubing 3m length	Unit: 05033241064031 Outer: 05033241064048

Version History:

Version	Details of amendments	Active date
Version 1	First Issue under MDR 2017/745	29/July/2022
Version 2	Removal of code CT-4340	20/January/2023
Version 3	Addition of standards EN ISO 11607-1:2019 and EN ISO 11607-2:2019. Corrected typo error in version history v2.	06/July/2023
Version 4	Addition of code AT-4000. Removal of EN ISO 20696:2018, inclusion of EN ISO 10993-7:2008 / AMD1:2019 and EN ISO 11135:2014	31/January/2024
Versions 5	Addition of product codes CTS-4328, CTS-4338, CTS-4378	16/May/2024