

EC DECLARATION OF CONFORMITY FOR SURGICAL SUCTION PROBES

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
EMDN:	Vacuum and Cavity Drainage Systems A06010103 - Devices for administration, withdrawal and collection - Cannulas and tips for aspiration and irrigation, single-use
Product Name:	Surgical Suction Probes
Product Codes:	Refer to Appendix 2
Device Classification:	Class IIa, Rule 5 and Rule 6 according to Annex VIII, MDR (EU) 2017/745
Common Specifications:	N/A
Intended use:	Pennine's Surgical Suction Probe range of devices are hand operated, single use, and are used as a conduit to remove bodily fluids and secretions, surgical tissue debris, irrigation fluids and gasses. They are used in surgical sites and body cavities to facilitate observation and/or to clear an obstruction. To be used on all patient populations by clinicians and trained homecare users, in clinical setting, homecare and emergency settings.
Basic UDI-DI:	UDI-DI - 5033241SURGICALSUCTIONBE
Notified Body:	BSI Group The Netherlands B.V
Notified Body Number:	2797
Conformity Assessment	Annex IX Chapters I and III of EU MDR 2017/745

Route:

MDR Certificate Number: 766979

GMDN: 35917 - Surgical/emergency suction cannula, non-illuminating, single-use. An atraumatic, invasive, hand-operated, single-lumen, rigid/semi-rigid tube designed as a conduit for aspiration of body cavities, wounds, or surgical sites to facilitate observation and/or to clear an airway obstruction. It is not dedicated to dental, intrauterine, or liposuction procedures, and is neither an ophthalmic nor an intravascular device; it is not designed for surgical irrigation. Sometimes referred to as a suction tube or tip, it may incorporate a handle with side valve(s)/hole(s), and may be provided with a stylet, sheath, and/or connection tubing; it does not include a light source or fibreoptic bundle. This is a single-use device.

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: 10-July-2023

M. Arun

Name: **Arun Mahendran**

Position: **Head of Quality and 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.
BS 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.

Appendix 2 Product List:

Product Code	Description	UDI-DI
LY-3400	LY-3400 MINI, FG15 LINK YANKAUER	Unit: 05033241019024 Outer: 05033241140629
LY-3401	LY-3401 MINI, V.C, 15FG LINK YANKAUER	Unit: 05033241019055 Outer: 05033241140636
LY-3500	LY-3500 MINI-FINE, 12FG LINK YANKAUER	Unit: 05033241019093 Outer: 05033241140582
LY-3501	LY-3501 MINI-FINE, V.C, 12FG LINK YANKAUER	Unit: 05033241019123 Outer: 05033241140599
LY-3600	LY-3600 MIDI, 18FG LINK YANKAUER	Unit: 05033241019192 Outer: 05033241140513
LY-3600/PR	LY-3600/PR MIDI, 18FG LINK YANKAUER	Unit: 05033241019222 Outer: 05033241141244
LY-3601	LY-3601 MIDI, V.C, 18FG LINK YANKAUER	Unit: 05033241019246 Outer: 05033241140520
LY-3700	LY-3700 MAXI, 22FG LINK YANKAUER	Unit: 05033241019390 Outer: 05033241140377
LY-3700/F	LY-3700/F WITH FG24 CONNECTOR LINK YANKAUER	Unit: 05033241019420 Outer: 05033241143927
LY-3700/RF/FF	LY-3700/RF/FF MAXI-F, 22FG LINK YANKAUER	Unit: 05033241019451 Outer: 05033241140384
LY-3701	LY-3701 MAXI, V.C, 22FG LINK YANKAUER	Unit: 05033241019482 Outer: 05033241140391
LY-3702	LY-3702 MAXI, NO SIDE EYES LINK YANKAUER	Unit: 05033241019512 Outer: 05033241143026
LY-3800	LY-3800 MAXI-PLUS, 28FG LINK YANKAUER	Unit: 05033241019529 Outer: 05033241140421

LY-3801	LY-3801 MAXI-PLUS, V.C, 28FG LINK YANKAUER	Unit: 05033241019550 Outer: 05033241140438
LY-3803	LY-3803 MAXI-PLUS, V.C LINK YANKAUER	Unit: 05033241019581 Outer: 05033241140445
LY-4400	LY-4400 MINI, 15FG SUPER TIP LINK YANKAUER	Unit: 05033241019642 Outer: 05033241141404
LY-4401	LY-4401 MINI, V.C, 15FG SUPER TIP LINK YANKAUER	Unit: 05033241019666 Outer: 05033241141381
LY-4420	LY-4420 MINI with 2 SIDE EYES SUPER TIP LINK YANKAUER	Unit: 05033241019680 Outer: 05033241141961
LY-4500	LY-4500 MINI-FINE, 12FG SUPER TIP LINK YANKAUER	Unit: 05033241019703 Outer: 05033241141480
LY-4500/NL	LY-4500/NL MINI-FINE, 12FG SUPER TIP LINK YANKAUER	Unit: 05033241019727 Outer: 05033241163192
LY-4501	LY-4501 MINI-FINE, V.C, 12FG SUPER TIP LINK YANKAUER	Unit: 05033241019758 Outer: 05033241141497
LY-4501/NL	LY-4501/NL MINI-FINE, V.C, 12FG SUPER TIP LINK YANKAUER	Unit: 05033241019772 Outer: 05033241142753
LY-4600	LY-4600 MIDI, 18FG SUPER TIP LINK YANKAUER	Unit: 05033241019826 Outer: 05033241140810
LY-4600/PR	LY-4600/PR MIDI, 18FG SUPER TIP LINK YANKAUER	Unit: 05033241019857 Outer: 05033241142739
LY-4601	LY-4601 MIDI, V.C, 18FG SUPER TIP LINK YANKAUER	Unit: 05033241019888 Outer: 05033241140827
LY-4700	LY-4700 MAXI, 22FG SUPER TIP LINK YANKAUER	Unit: 05033241019925 Outer: 05033241140834
LY-4700/PR	LY-4700/PR MAXI, 22FG SUPER TIP LINK YANKAUER	Unit: 05033241019949 Outer: 05033241141725
LY-4701	LY-4701 MAXI, V.C, 22FG SUPER TIP LINK YANKAUER	Unit: 05033241019970 Outer: 05033241140841
LYS-5430	LYS-5430 3.0m, 6mm, MINI LINK YANKAUER SET	Unit: 05033241020785 Outer: 05033241160030
LYS-5520	LYS-5520 2.0m, 6mm, MINI-FINE TIP LINK YANKAUER SET	Unit: 05033241020815 Outer: 05033241163963
LYS-5530	LYS-5530 3.0m, 6mm, MINI-FINE TIP LINK YANKAUER SET	Unit: 05033241020891 Outer: 05033241163826
LYS-5531	LYS-5531 3.0m, 6mm, MINI-FINE TIP, V.C. LINK YANKAUER SET	Unit: 05033241020945 Outer: 05033241160078
LYS-5620	LYS-5620 2.0m, 6mm, MIDI LINK YANKAUER SET	Unit: 05033241020976 Outer: 05033241163949
LYS-5621	LYS-5621 2.0m, 6mm, MIDI, V.C. LINK YANKAUER SET	Unit: 05033241021010 Outer: 05033241164038
LYS-5630	LYS-5630 3.0m, 6mm, MIDI LINK YANKAUER SET	Unit: 05033241021034 Outer: 05033241163840
LYS-5631	LYS-5631 3.0m, 6mm, MIDI, V.C. LINK YANKAUER SET	Unit: 05033241021089 Outer: 05033241163987
LYS-5720	LYS-5720 2.0m, 6mm, MAXI. LINK YANKAUER SET	Unit: 05033241021126 Outer: 05033241163932
LYS-5721	LYS-5721 2.0m, 6mm, MAXI, V.C. LINK YANKAUER SET	Unit: 05033241021164 Outer: 05033241163925
LYS-5730	LYS-5730 3.0m, 6mm, MAXI. LINK YANKAUER SET	Unit: 05033241021195 Outer: 05033241163864
LYS-5731	LYS-5731 3.0m, 6mm, MAXI, V.C. LINK YANKAUER SET	Unit: 05033241021232 Outer: 05033241160115
LYS-6620	LYS-6620 2.2m, 7mm, MIDI LINK YANKAUER SET	Unit: 05033241021331 Outer: 05033241161532
LYS-6830	LYS-6830 3.0m, 7mm, MAXI-PLUS LINK YANKAUER SET	Unit: 05033241021447 Outer: 05033241160153

LYS-7730	LYS-7730 3.0m, 8mm, MAXI LINK YANKAUER SET	Unit: 05033241021560 Outer: 05033241163796
MP-3802	MP-3802 6.8mm, 14cm, M SUCTION PROBE	Unit: 05033241022086 Outer: 05033241140179
SP-3800	SP-3800 6.8mm, 245mm, M SUCTION PROBE	Unit: 05033241031682 Outer: 05033241140711
SP-3900	SP-3900 250mm, M FLAT TIP SUCTION PROBE	Unit: 05033241031743 Outer: 05033241140735
SP-4200	SP-4200 FG 30, 250mm. MAXI SUCTION PROBE	Unit: 05033241031798 Outer: 05033241140759
SP-4300	SP-4300 FG 30, 255mm. MAXI FLAT TIP SUCTION PROBE	Unit: 05033241031828 Outer: 05033241140766
SPS-5020G	SPS-5020G 2.0m, 6mm SUCTION PROBE SET	Unit: 05033241031934 Outer: 05033241160726
SPS-5020W	SPS-5020W 2.0m, 6mm SUCTION PROBE SET	Unit: 05033241031941 Outer: 05033241160733
SPS-5021	SPS-5021 2.0m, 6mm, V.C. SUCTION PROBE SET	Unit: 05033241031958 Outer: 05033241163888
SPS-5022	SPS-5022 2.1m, 6mm SUCTION PROBE SET	Unit: 05033241032023 Outer: 05033241163918
SPS-5030W	SPS-5030W 3.0m, 6mm SUCTION PROBE SET	Unit: 05033241032061 Outer: 05033241160399
SPS-6020	SPS-6020 2.0m, 8mm MAXI SUCTION PROBE SET	Unit: 05033241032344 Outer: 05033241160832
SYS-5920	SYS-5920 2.0m, 6mm POOLE SUCTION PROBE SET	Unit: 05033241033075 Outer: 05033241160702
SYS-5923	SYS-5923 2.0m, 6mm POOLE SUCTION PROBE SET	Unit: 05033241033112 Outer: 05033241161983
SYS-5930	SYS-5930 3.0m, 6mm POOLE SUCTION PROBE SET	Unit: 05033241033129 Outer: 05033241160351
YS-3000	YS-3000 265mm SUCTION PROBE	Unit: 05033241035109 Outer: 05033241140773
YS-3001	YS-3001 265mm, VC SUCTION PROBE	Unit: 05033241035123 Outer: 05033241140780
YS-3006	YS-3006 300mm POOLE SUCTION PROBE	Unit: 05033241035215 Outer: 0503324114065
YS-3008	YS-3008 300mm POOLE SUCTION PROBE WITH CURVED SUCTION TIP	Unit: 05033241035253 Outer: 05033241141084
YS-3068	YS-3068 FG/CH6(2.0mm), 16.8cm, V.C. MICROFLEX SUCTION PROBE	Unit: 05033241035376 Outer: 05033241140469
YS-3088	YS-3088 FG/CH8(2.7mm) 22.3cm, V.C. MICROFLEX SUCTION PROBE	Unit: 05033241035383 Outer: 05033241140476
YS-3088/Z	YS-3088/Z FG/CH8(2.7mm) 16.8cm, V.C. MICROFLEX SUCTION PROBE -ZOELLNER	Unit: 05033241035406 Outer: 05033241140483
YS-3108	YS-3108 FG/CH10(3.3mm) 22.3cm, V.C. MICROFLEX SUCTION PROBE	Unit: 05033241035420 Outer: 05033241140490
YS-3128	YS-3128 FG/CH12(4.0mm) 21.3cm, V.C. MICROFLEX SUCTION PROBE	Unit: 05033241035444 Outer: 05033241140506
YS-3128/20	YS-3128/20 FG/CH12(4.0mm) 29.8cm, V.C. ENDOFLEX SUCTION PROBE	Unit: 05033241035475 Outer: 05033241140247 Inner: 05033241141992
YS-3128/26	YS-3128/26 FG/CH12(4.0mm) 35.8cm, V.C. ENDOFLEX SUCTION PROBE	Unit: 05033241035482 Outer: 05033241140254 Inner: 05033241141978
YS-3128/40	YS-3128/40 FG/CH12(4.0mm) 49.8cm, V.C. ENDOFLEX SUCTION PROBE	Unit: 05033241035499 Outer: 05033241140261 Inner: 05033241141985
YS-3128/60	YS-3128/60 FG/CH12(4.0mm) 69.8cm, V.C. ENDOFLEX SUCTION PROBE	Unit: 05033241035505 Outer: 05033241140278

YS-3148/14	YS-3148/14 FG/CH14(4.7mm) 22.3cm, V.C MICROFLEX SUCTION PROBE	Unit: 05033241035529 Outer: 05033241141145
LY-3400/BULK	LY-3400 MINI, FG15 LINK YANKAUER BULK	Unit: 05033241019031 Outer: 05033241141176
LY-3401/BULK	LY-3401 MINI, V.C, 15FG LINK YANKAUER BULK	Unit: 05033241019062 Outer: 05033241141183
LY-3500/BULK	LY-3500 MINI-FINE, 12FG LINK YANKAUER BULK	Unit: 05033241019109 Outer: 05033241141190
LY-3501/BULK	LY-3501 MINI-FINE, V.C, 12FG LINK YANKAUER BULK	Unit: 05033241019130 Outer: 05033241141206
LY-3600/BULK	LY-3600 MIDI, 18FG LINK YANKAUER BULK	Unit: 05033241019208 Outer: 05033241141237
LY-3600/PR/BULK	LY-3600/PR MIDI, 18FG LINK YANKAUER BULK	Unit: 05033241019239 Outer: 05033241142265
LY-3601/BULK	LY-3601 MIDI, V.C, 18FG LINK YANKAUER BULK	Unit: 05033241019253 Outer: 05033241141251
LY-3700/BULK	LY-3700 MAXI, 22FG LINK YANKAUER BULK	Unit: 05033241019413 Outer: 05033241141275
LY-3701/BULK	LY-3701 MAXI, V.C, 22FG LINK YANKAUER BULK	Unit: 05033241019505 Outer: 05033241141305
LY-3800/BULK	LY-3800 MAXI-PLUS, 28FG LINK YANKAUER BULK	Unit: 05033241019536 Outer: 05033241141312
LY-3801/BULK	LY-3801 MAXI-PLUS, V.C, 28FG LINK YANKAUER BULK	Unit: 05033241019567 Outer: 05033241141329
LY-4400/BULK	LY-4400 MINI, 15FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019659 Outer: 05033241143675
LY-4401/BULK	LY-4401 MINI, V.C, 15FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019673 Outer: 05033241143682
LY-4420/BULK	LY-4420 MINI with 2 SIDE EYES SUPER TIP LINK YANKAUER BULK	Unit: 05033241063096 Outer: 05033241063102
LY-4500/BULK	LY-4500 MINI-FINE, 12FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019710 Outer: 05033241142104
LY-4500/NL/BULK	LY-4500/NL MINI-FINE, 12FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019734 Outer: 05033241142258
LY-4501/BULK	LY-4501 MINI-FINE, V.C, 12FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019765 Outer: 05033241142227
LY-4501/NL/BULK	LY-4501/NL MINI-FINE, V.C, 12FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019789 Outer: 05033241142401
LY-4600/BULK	LY-4600 MIDI, 18FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019833 Outer: 05033241162409
LY-4600/PR/BULK	LY-4600/PR MIDI, 18FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019864 Outer: 05033241143620
LY-4601/BULK	LY-4601 MIDI, V.C, 18FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019895 Outer: 05033241142272
LY-4700/BULK	LY-4700 MAXI, 22FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019932 Outer: 05033241142029
LY-4700/PR/BULK	LY-4700/PR MAXI, 22FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019956 Outer: 05033241143637
LY-4701/BULK	LY-4701 MAXI, V.C, 22FG SUPER TIP LINK YANKAUER BULK	Unit: 05033241019987 Outer: 05033241142050
LYS-5520/BULK	LYS-5520 2.0m, 6mm, MINI-FINE TIP LINK YANKAUER SET BULK	Unit: 05033241020822 Outer: 05033241163970
LYS-5530/BULK	LYS-5530 3.0m, 6mm, MINI-FINE TIP LINK YANKAUER SET BULK	Unit: 05033241020907 Outer: 05033241163833
LYS-5531/BULK	LYS-5531 3.0m, 6mm, MINI-FINE TIP, V.C. LINK YANKAUER SET BULK	Unit: 05033241063119 Outer: 05033241063112
LYS-5620/BULK	LYS-5620 2.0m, 6mm, MIDI LINK YANKAUER SET BULK	Unit: 05033241020983 Outer: 05033241162300

LYS-5621/BULK	LYS-5621 2.0m, 6mm, MIDI, V.C. LINK YANKAUER SET BULK	Unit: 05033241063133 Outer: 05033241063140
LYS-5630/BULK	LYS-5630 3.0m, 6mm, MIDI LINK YANKAUER SET BULK	Unit: 05033241021041 Outer: 05033241163857
LYS-5631/BULK	LYS-5631 3.0m, 6mm, MIDI, V.C. LINK YANKAUER SET BULK	Unit: 05033241063157 Outer: 05033241063164
LYS-5720/BULK	LYS-5720 2.0m, 6mm, MAXI. LINK YANKAUER SET BULK	Unit: 05033241000596 Outer: 05033241021133
LYS-5721/BULK	LYS-5721 2.0m, 6mm, MAXI, V.C. LINK YANKAUER SET BULK	Unit: 05033241021171 Outer: 05033241163956
LYS-5730/BULK	LYS-5730 3.0m, 6mm, MAXI. LINK YANKAUER SET BULK	Unit: 05033241021201 Outer: 05033241162621
LYS-5731/BULK	LYS-5731 3.0m, 6mm, MAXI, V.C. LINK YANKAUER SET BULK	Unit: 05033241063171 Outer: 05033241063188
LYS-6620/BULK	LYS-6620 2.2m, 7mm, MIDI LINK YANKAUER SET BULK	Unit: 05033241021348 Outer: 05033241162614
LYS-6830/BULK	LYS-6830 3.0m, 7mm, MAXI-PLUS LINK YANKAUER SET BULK	Unit: 05033241021454 Outer: 05033241163444
LYS-7730/BULK	LYS-7730 3.0m, 8mm, MAXI LINK YANKAUER SET BULK	Unit: 05033241021577 Outer: 05033241163802
SP-3800/BULK	SP-3800 6.8mm, 245mm, M SUCTION PROBE BULK	Unit: 05033241031699 Outer: 05033241142302
SP-3900/BULK	SP-3900 250mm, M FLAT TIP SUCTION PROBE BULK	Unit: 05033241031750 Outer: 05033241143439
SP-4200/BULK	SP-4200 FG 30, 250mm. MAXI SUCTION PROBE BULK	Unit: 05033241031804 Outer: 05033241162447
SP-4300/BULK	SP-4300 FG 30, 255mm. MAXI FLAT TIP SUCTION PROBE BULK	Unit: 05033241031835 Outer: 05033241142760
SPS-5020/W/BULK	SPS-5020W 2.0m, 6mm SUCTION PROBE SET BULK	Unit: 05033241063218 Outer: 05033241063225
SPS-5021/BULK	SPS-5021 2.0m, 6mm, V.C. SUCTION PROBE SET BULK	Unit: 05033241031965 Outer: 05033241163895
SPS-6020/BULK	SPS-6020 2.0m, 8mm MAXI SUCTION PROBE SET BULK	Unit: 05033241032351 Outer: 05033241163215
SYS-5920/BULK	SYS-5920 2.0m, 6mm POOLE SUCTION PROBE SET BULK	Unit: 05033241000206 Outer: 05033241033082
SYS-5930/BULK	SYS-5930 3.0m, 6mm POOLE SUCTION PROBE SET BULK	Unit: 05033241036243 Outer: 05033241036250
YS-3000/BULK	YS-3000 265mm SUCTION PROBE BULK	Unit: 05033241035116 Outer: 05033241141411
YS-3001/BULK	YS-3001 265mm, VC SUCTION PROBE BULK	Unit: 05033241035130 Outer: 05033241141473
YS-3006/BULK	YS-3006 300mm POOLE SUCTION PROBE BULK	Unit: 05033241035222 Outer: 05033241141466
YS-3008/BULK	YS-3008 300mm POOLE SUCTION PROBE WITH CURVED SUCTION TIP BULK	Unit: 05033241035260 Outer: 05033241143064
YS-3128/BULK	YS-3128 FG/CH12(4.0mm) 21.3cm, V.C. MICROFLEX SUCTION PROBE BULK	Unit: 05033241035512 Outer: 05033241142135
YS-3148/14/BULK	YS-3148/14 FG/CH14(4.7mm) 22.3cm, V.C MICROFLEX SUCTION PROBE BULK	Unit: 05033241063195 Outer: 05033241063201