

## EC DECLARATION OF CONFORMITY FOR SURGICAL SUCTION PROBE

This is a declaration made in accordance with the requirements of the relevant provisions of Annex I of the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC and the UK Medical Devices Regulations 2002, SI 2002/618 as amended by SI 2008 / 2936 and have been subject to the conformity assessment procedures laid out in Annex V.

<b>Legal Name:</b>	IVOR SHAW LIMITED t/a PENNINE HEALTHCARE
<b>Business Address:</b>	300 City Gate London Road Derby DE24 8WY United Kingdom
<b>EU Authorised Representative:</b>	Advena Ltd. Tower Business Centre, 2 <sup>nd</sup> Floor, Tower Street, Swatar, BKR 4013, Malta
<b>Medical Devices:</b>	Surgical Suction Probe
<b>Classification:</b>	Class IIa, Rule 6
<b>GMDN:</b>	35917
<b>Intended use:</b>	Pennine's Surgical Suction Probe range of devices are hand operated, single use, sterile devices. They are used as a conduit to remove bodily fluids and secretions, surgical tissue debris and irrigation fluids. They are used in surgical sites and body cavities to facilitate observation and/or to clear an obstruction.
<b>Category:</b>	MD 0106 Non-active instruments
<b>Under the supervision of the Notified Body:</b>	BSI Group The Netherlands B.V
<b>With the Notified Body Number:</b>	2797
<b>Notified Body Certificate Number:</b>	CE 648427
<b>Conformity of assessment:</b>	EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with Production Quality Assurance outlined in Annex V.

Signed By:

Date: 26 March 2021

*M. Arun*

Name: **Arun Mahendran**

Position: **Head of Regulatory Affairs**

On behalf of IVOR SHAW LTD t/a Pennine Healthcare, Derby, United Kingdom. Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

### Appendix 1 Applicable Standards:

Standard / Document Name	Description
ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes
ISO 14971:2019	Medical devices. Application of risk management to medical devices
IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
EN 1041:2008	Information supplied by the manufacturer of medical devices
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
ISO 14644-1:2015	Cleanrooms and associated controlled environments. Classification of air cleanliness by particle concentration
ISO 11135:2014 +A1:2019	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
LY-3400	Yankauer Link Short Mini 15fg 190mm
LY-3401	Yankauer Link Short Mini VC 15fg 190cm
LY-3500	Yankauer Link Mini Fine Tip 12fg 270mm
LY-3501	Yankauer Link Mini Fine Tip VC 12fg 270mm
LY-3600	Yankauer Link Midi Tip 30 Degree 18fg 280mm
LY-3600/PR	Yankauer Link Midi Tip 10 Degree 18fg 280mm
LY-3601	Yankauer Link Midi Tip VC 18fg 280mm
LY-3700	Yankauer Link Maxi Tip 22fg 275mm
LY-3700/F	Yankauer Link Maxi Tip with Blue Female Connector 22fg 275mm
LY-3700/RF/FF	Yankauer Link Maxi Tip with Straight Connector 22fg 275mm
LY-3701	Yankauer Link Maxi Tip VC 22fg 275mm
LY-3702	Yankauer Link Maxi Tip 22fg 275mm No Side Eyes
LY-3800	Yankauer Link Maxi Plus Tip 28fg 280mm
LY-3801	Yankauer Link Maxi Plus Tip VC 28fg 280mm
LY-3803	Yankauer Link Maxi Plus Tip VC 28fg 280mm No Side Eyes
LY-4400	Yankauer Link Short Mini Super Tip 15fg 195mm
LY-4401	Yankauer Link Mini Super Tip VC 15fg 195mm
LY-4420	Yankauer Link Short Mini Super Tip 15fg 195mm No Side Eyes
LY-4500	Yankauer Link Mini Fine Super Tip 12fg 275mm No Side Eyes
LY-4500/NL	Yankauer Link Mini Fine Super Tip 10 Degree 12fg 275mm No Side Eyes
LY-4501	Yankauer Link Mini Fine Super Tip VC 12fg 275mm
LY-4501/NL	Yankauer Link Mini Fine Super Tip VC 10 Degree 12fg 275mm No Side Eyes
LY-4600	Yankauer Link Midi Super Tip 18fg 280mm
LY-4600/PR	Yankauer Link Midi Super Tip 10 Degree 18fg 280mm
LY-4601	Yankauer Link Midi Formed Super Tip VC 18fg 280mm
LY-4700	Yankauer Link Maxi Formed Super Tip 22fg 275mm
LY-4700/PR	Yankauer Link Maxi 10 Degree Super Tip 22fg 275mm
LY-4701	Yankauer Link Maxi Super Tip VC 22fg 275mm
LYS-5430	Yankauer Link Set, Tube 6mm x 3m, Yankauer Short Mini LY-3400
LYS-5520	Yankauer Link Set, Tube 6mm x 2m, Yankauer Mini Fine LY-3500

LYS-5530	Yankauer Link Set, Tube 6mm x 3m, Yankauer Mini Fine LY-3500
LYS-5531	Yankauer Link Set, Tube 6mm x 3m, Yankauer Mini Fine VC LY-3501
LYS-5620	Yankauer Link Set, Tube 6mm x 2m, Yankauer Midi LY-3600
LYS-5621	Yankauer Link Set, Tube 6mm x 2m, Yankauer Midi VC LY-3601
LYS-5630	Yankauer Link Set, Tube 6mm x 3m, Yankauer Midi LY-3600
LYS-5631	Yankauer Link Set, Tube 6mm x 3m, Yankauer Midi VC LY-3601
LYS-5720	Yankauer Link Set, Tube 6mm x 2m, Yankauer Maxi LY-3700
LYS-5721	Yankauer Link Set, Tube 6mm x 2m, Yankauer Maxi VC LY-3701
LYS-5730	Yankauer Link Set, Tube 6mm x 3m, Yankauer Maxi LY-3700
LYS-5731	Yankauer Link Set, Tube 6mm x 3m, Yankauer Maxi VC LY-3701
LYS-6620	Yankauer Link Set, Tube 7mm x 2.2m, Yankauer Midi LY-3600
LYS-6830	Yankauer Link Set, Tube 7mm x 3m, Yankauer Jumbo LY-3800
LYS-7730	Yankauer Link Set, Tube 8mm x 3m, Yankauer Maxi LY-3700
MP-3802	Suction Probe Short 20fg 120mm No Side Eyes
SP-3800	Suction Probe, Male Connector 20fg 245mm
SP-3900	Suction Probe, Flat Tip, Male Connector 20fg 250mm
SP-4200	Suction Probe, Maxi, 30fg 280mm
SP-4300	Suction Probe, Flat Tip Maxi 30fg 255mm
SPS-5020G	Suction Probe Set, Tube 6mm x 2m, Standard Probe
SPS-5020W	Suction Probe Set, Tube 6mm x 2m, Standard Probe
SPS-5021	Suction Probe Set, Tube 6mm x 2m, Standard Probe VC SP-3201
SPS-5022	Suction Probe Set, Tube 6mm x 2.1m, Standard Probe
SPS-5030W	Suction Probe Set, Tube 6mm x 3m, Standard Probe
SPS-6020	Suction Probe Set, Tube 8mm x 2m, Probe Maxi SP-4200
SYS-5520	Yankauer Set, Tube 6mm x 2m, Derby Yankauer Straight Tip YS-3014
SYS-5820	Yankauer Set, Tube 6mm x 2m, Derby Yankauer Sump Tip YS-3004
SYS-5821	Yankauer Set, Tube 6mm x 2m, Derby Yankauer Sump Tip VC YS-3005
SYS-5821/GG	Yankauer Set, Tube 6mm x 2m, Derby Yankauer Sump Tip VC YS-3005
SYS-5830	Yankauer Set, Tube 6mm x 3m, Derby Yankauer Sump tip (YS-3004)
SYS-5831	Yankauer Set, Tube 6mm x 3m, Derby Yankauer Sump tip VC (YS-3005)
SYS-5920	Poole Suction Set, Tube 6mm x 2m, Poole Flexible Straight YS-3006
SYS-5923	Poole Suction Set, Tube 6mm x 2m, Poole Flexible Angled YS-3008
YS-3000	Suction Probe, Straight Tip 20fg 265mm
YS-3001	Suction Probe, Straight Tip VC 20fg 265mm
YS-3004	Yankauer Derby, Sump Tip 24fg 265mm
YS-3005	Yankauer Derby, Sump Tip VC 24fg 265mm
YS-3006	Poole Suction Flexible Straight 20fg 300mm
YS-3007	Poole Suction Rigid Straight 15fg 300mm
YS-3008	Poole Suction Flexible Angled 20fg 300mm
YS-3014	Yankauer Derby, Straight Tip 24fg 265mm
YS-3015	Yankauer Derby, Straight Tip VC 24fg 265mm
YS-3068	Microflex Suction VC 6fg 11cm
YS-3088	Microflex Suction VC 8fg 15cm
YS-3088/Z	Microflex Suction VC 8fg 11cm
YS-3108	Microflex Suction VC 10fg 15cm
YS-3128	Microflex Suction VC 12fg 15cm
YS-3128/20	Endoflex Suction VC 12fg 20cm
YS-3128/26	Endoflex Suction VC 12fg 26cm
YS-3128/40	Endoflex Suction VC 12fg 40cm
YS-3128/60	Endoflex Suction VC 12fg 60cm
YS-3148/14	Microflex Suction VC 14fg 16cm