Flexicare Medical Limited
Cwm Cynon Business Park,
Mountain Ash
CF45 4ER
United Kingdom- UK

22/04/2024

Confirmation Letter Reference: CLNB1639 - GBPC 05884

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Flexicare Medical Limited
Cwm Cynon Business Park,
Mountain Ash
CF45 4ER
United Kingdom- UK
SRN: GB-MF-000034163

Authorised Representative:
Flexicare Deutschland GmbH
Ohlenhohnstrasse 34,
53819 Neunkirchen-Seelscheid,
Germany
SRN: DE-AR-000029825

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the

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devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV NB1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Suction Tubing (Sterile) 5055788700000302FH	Class Is	Suction Tubing	N/A	GB19/964678; NB1639
Drainable Bags (Sterile) 5055788700001907GY	Class Is	Suction Tubing	N/A	GB19/964678; NB1639
Leg Bags (Sterile) 5055788700001906GW	Class Is	Leg Bags (Sterile)	N/A	GB19/964678; NB1639
Non-Drainable Bags (Sterile) 5055788700001908H2	Class Is	Non-Drainable Bags (Sterile)	N/A	GB19/964678; NB1639
Oropharyngeal Airways (Sterile Guedel) 5055788700003002FP	Class Is	Oropharyngeal Airways (Sterile Guedel)	N/A	GB19/964678; NB1639
Oropharyngeal Airways (Williams) 5055788700003004FT	Class Is	Oropharyngeal Airways (Williams)	N/A	GB19/964678; NB1639
Breathing System Components and Accessories (Sterile Safety Caps) 5055788700056C04LZ	Class Is	Breathing System Components and Accessories (Sterile Safety Caps)	N/A	GB19/964678; NB1639
Bougies and Stylets (Bougies) 5055788700010801GK	Class Is	Bougies	N/A	GB19/964678; NB1639
Bougies and Stylets (Stylets) 5055788700010802GM	Class Is	Bougies	N/A	GB19/964678; NB1639
Nasopharyngeal Airways (Sterile) 5055788700011401G6	Class Is	Nasopharyngeal Airways	N/A	GB19/964678; NB1639
Meatal Dilators (Sterile) 5055788700011601GG	Class Is	Meatal Dilators (Sterile)	N/A	GB19/964678; NB1639

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Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Intermittent and Short Term Use Catheters (Hydrophillic) 5055788700011701GM	Class Is	Intermittent and Short Term Use Catheters (Hydrophillic)	N/A	GB19/964678; NB1639
Intermittent and Short Term Use Catheters (Lubricated) 5055788700011702GP	Class Is	Intermittent and Short Term Use Catheters (Lubricated)	N/A	GB19/964678; NB1639
Intermittent and Short Term Use Catheters (Plain) 5055788700011703GR	Class Is	Intermittent and Short Term Use Catheters (Plain)	N/A	GB19/964678; NB1639
EZ-Flow Catheter Valves 5055788700001909H4	Class Is	EZ-Flow Catheter Valves	N/A	GB19/964678; NB1639
BritePro Solo Handle and Fibre Optic Blades (Blade, Sterile 5055788700120A02JM	Class Is	BritePro Solo Handle and Fibre Optic Blades (Blade, Sterile	N/A	GB19/964678; NB1639
Video Laryngoscope Handle with Blade 5055788700120E01K7	Class Is	Laryngoscope Blade	N/A	GB19/964678; NB1639
BritePro Solo Handle and Fibre Optic Blades (Handle, Sterile) 5055788700120A03JP	Class Is	BritePro Solo Handle and Fibre Optic Blades (Handle, Sterile)	N/A	GB19/964678; NB1639
BritePro Solo Handle and Fibre Optic Blades (Laryngoscope, Sterile) 5055788700120A06JV	Class Is	BritePro Solo Handle and Fibre Optic Blades (Laryngoscope, Sterile)	N/A	GB19/964678; NB1639
BritePro Omni (Sterile) 5055788700120C02JX	Class Is	BritePro Omni (Sterile)	N/A	GB19/964678; NB1639

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Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Urimeter 5055788700004001FU	Class Is	Urine drainage bags	N/A	GB19/964678; NB1639
Manual Resuscitator Bags	Class IIa	Manual Resuscitator Bags	N/A	GB19/964677; NB1639
CO2 Absorbents	Class IIa	CO2 Absorbents	N/A	GB19/964677; NB1639
Nasal Cannulas	Class IIa	Nasal Cannulas	N/A	GB19/964677; NB1639
Oxygen Masks	Class IIa	Oxygen Masks	N/A	GB19/964677; NB1639
Oxygen Therapy Accessories	Class IIa	Oxygen Therapy Accessories	N/A	GB19/964677; NB1639
Resuscitation Circuits	Class IIa	Resuscitation Circuits	N/A	GB19/964677; NB1639
Resuscitation Units	Class IIa	Resuscitation Units	N/A	GB19/964677; NB1639
Filter – Electrostatic	Class IIa	Filter – Electrostatic	N/A	GB19/964677; NB1639
Filters – Mechanical	Class IIa	Filters – Mechanical	N/A	GB19/964677; NB1639
Nebulisers	Class IIa	Nebulisers	N/A	GB19/964677; NB1639
Anaesthesia Circuits	Class IIa	Anaesthesia Circuits	N/A	GB19/964677; NB1639
Ventilator Circuits	Class IIa	Ventilator Circuits	N/A	GB19/964677; NB1639
Breathing Systems Components and Accessories	Class IIa	Breathing Systems Components and Accessories	N/A	GB19/964677; NB1639

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Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Humidification Circuits	Class IIa	Humidification Circuits	N/A	GB19/964677; NB1639
Laryngeal Mask Airways	Class IIa	Laryngeal Mask Airways	N/A	GB19/964677; NB1639
Heat and Moisture Exchange Filters (HMEFs)	Class IIa	Heat and Moisture Exchange Filters (HMEFs)	N/A	GB19/964677; NB1639
Heat and Moisture Exchangers (HMEs)	Class IIa	Heat and Moisture Exchangers (HMEs)	N/A	GB19/964677; NB1639
Video Stylets	Class IIa	Video Stylets	N/A	GB19/964677; NB1639
Intermittent and Short Term Use Catheters	Class IIa	Short term Use Urinary Catheter	N/A	GB19/964677; NB1639
Suction Catheters	Class IIa	Suction Catheters	N/A	GB19/964677; NB1639
Closed Suction Catheters	Class IIa	Closed Suction Catheters	N/A	GB19/964677; NB1639
Endotracheal Tubes	Class IIa	Endotracheal Tubes	N/A	GB19/964677; NB1639
Endoscopy Bite Block	Class IIa	Endoscopy Bite Block with O2 delivery and CO2 monitoring	N/A	GB19/964677; NB1639
Suction Yankauers	Class IIa	Suction Yankauers	N/A	GB19/964677; NB1639
Pocket Resuscitation First Aid Masks	Class IIa	Pocket Resuscitation First Aid Masks	N/A	GB19/964677; NB1639

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Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Anesthesia Facemasks	Class IIa	Anesthesia Facemasks	N/A	GB19/964677; NB1639
Sterile Stoma Plugs	Class IIa	Sterile Stoma Plugs	N/A	GB19/964677; NB1639
Altera Breathing Circuits	Class IIa	Altera Breathing Circuits	N/A	GB19/964677; NB1639
Silicone Foley Catheters FL9000	Class IIb	Silicone Foley Catheters FL9000	N/A	GB19/964677; NB1639
FL9000 (Adapter Leads)	Class IIb	FL9000 (Adapter Leads)	N/A	GB19/964677; NB1639
FL9000 (Temperature Probes)	Class IIb	FL9000 (Temperature Probes)	N/A	GB19/964677; NB1639
FL10000	Class IIb	FL10000	N/A	GB19/964677; NB1639
FL10000 (Adapter Leads)	Class IIb	FL10000 (Adapter Leads)	N/A	GB19/964677; NB1639
FL10000 (Temperature Probes)	Class IIb	FL10000 (Temperature Probes)	N/A	GB19/964677; NB1639
Booster Heater	Class IIb	Booster Heater – Respiratory Humidifier	N/A	GB19/964677; NB1639

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Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Suction Tubing (Non-Sterile) 5055788700000301FF	Class I	N/A	MDD self-certified
Drainage Bags (Stands) 5055788700001901GL	Class I	N/A	MDD self-certified
Drainage Bags (Securing Devices) 5055788700001902GN	Class I	N/A	MDD self-certified
Leg Bags (Non-Sterile) 5055788700001903GQ	Class I	N/A	MDD self-certified
2L Bags (Drainable) Neonatal 5055788700001904GS	Class I	N/A	MDD self-certified
2l Bags (Non-Drainable) 5055788700001905GU	Class I	N/A	MDD self-certified
Oropharyngeal Airways - Guedel Airways (Non-Sterile, Single Use) 5055788700030A01JH	Class I	N/A	MDD self-certified
Oropharyngeal Airways - Berman Airways (Non-Sterile, Single Use) 5055788700030B01JN	Class I	N/A	MDD self-certified
Jaw Opener (Non-Sterile, Single Use) 5055788700031A01JQ	Class I	N/A	MDD self-certified
ET Tube Holder (Non-Sterile, Single Use) 5055788700031B01JV	Class I	N/A	MDD self-certified
Magill Forceps (Non-Sterile, Single Use)	Class I	N/A	MDD self-certified

5055788700031C01K2			
Resuscitation Units (Mounting Brackets) 5055788700033B01KB	Class I	N/A	MDD self-certified
Filters - Electrostatic (Pulmonary Function Test Filter Nose Clip) 5055788700041B05KG	Class I	N/A	MDD self-certified
Ventilator Circuits (Headstrap for CPAP Mask) 5055788700056B01LN	Class I	N/A	MDD self-certified
Breathing System Components and Accessories (Non-Sterile Safety Caps) 5055788700056C33GS	Class I	N/A	MDD self-certified
Enema and Douche Devices (Non-Sterile, Single Use) 5055788700082A01LN	Class I	N/A	MDD self-certified
Single Use Laryngoscopes (Fibre Optic, Blade, Non-Sterile) 5055788700011501GB	Class I	N/A	MDD self-certified
Single Use Blades - Fiber Optic (Non-Sterile, Single Use) 5055788700120A01JK	Class I	N/A	MDD self-certified
LarySeal Cuff Inflator (Non-Sterile, Reusable) 5055788700120B01JQ	Class I	N/A	MDD self-certified
Single Use Laryngoscopes (Conventional, Blade) 5055788700120A07JX	Class I	N/A	MDD self-certified
Single Use Laryngoscopes (Fibre Optic, Laryngoscope, Non-Sterile) 5055788700120A05JT	Class I	N/A	MDD self-certified

Single Use Laryngoscopes (Fibre Optic, Handle, Non-Sterile) 5055788700120A04JR	Class I	N/A	MDD self-certified
BritePro Omni (Non-Sterile) 5055788700120C01JV	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Conventional, Laryngoscope) 5055788700120D03K6	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Conventional, Blade) 5055788700120D02K4	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Conventional, Handle) 5055788700120D01K2	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Fibre Optic, Laryngoscope) 5055788700120D06KC	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Fibre Optic, Blade) 5055788700120D05KA	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Fibre Optic, Handle) 5055788700120D04K8	Class I	N/A	MDD self-certified
NS SU Laryngoscopes (Non-Sterile, Single Use) 5055788700120F01KC	Class I	N/A	MDD self-certified
Endoscopy Bite Block (EasyGuard) 5055788700012401GD	Class I	N/A	MDD self-certified

FL9000 (Adapter Leads) 5055788700132A03KG	Class I	N/A	MDD self-certified
FL9000 (Accessories) 5055788700132A01KC	Class I	N/A	MDD self-certified
Breath Trainers 5055788700015301GV	Class I	N/A	MDD self-certified
ProVu Accessories – Displays 5055788700015501H7	Class I	N/A	MDD self-certified
ProVu Accessories – Wrist Holders 5055788700015503HB	Class I	N/A	MDD self-certified
ProVu Accessories – Stands 5055788700015502H9	Class I	N/A	MDD self-certified

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
22/04/2024	Version 1	Initial issue

SGS NB1639 - Confirmation letter Regu (EU) 607

Manufacturer's Declaration[1]

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Flexicare Medical Ltd
Manufacturer address and contact details	Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK. Contact Name – Dr Gurge Phull Contact Number – 01443474647 Contact Role – Quality and Regulatory Director
Single Registration Number (SRN) (if available)	GB-MF-000034163

Authorised Representative name (if applicable)	Flexicare Deutschland GmbH

[1]SGS has confirmed that under the new legislation (2023/607) Notified Bodies will not be allowed to reissue an MDD CE Certificate with extended dates, the legislation itself extends the validity of the existing certificates and may be viewed at the following link: https://eur-lex.europa.eu/eli/reg/2023/607/oj. This declaration template has been provided to Flexicare Medical Limited by the Notified Body SGS Belgium NV (CE 1639) for Flexicare to formally declare conformity to the relevant parts of 2023/607.
An application for MDR 2017/745 has been submitted by Flexicare to SGS in June 2022. SGS policy is that no letter regarding MDR may be given by them until they have finished the initial review of this application and signed an MDR contract with Flexicare. However parties wishing to confirm the validity of this letter and the ability of Flexicare to continue to legally place CE Mark devices on the market may contact SGS by email on sgsmedicaluk@sgs.com

Authorised Representative address and contact details	Ohlenhohnstrasse 34, 53819 Neunkirchen-Seelscheid, Germany Contact Name – Dr Gurge Phull Contact Number – 01443474647 Contact Role – Quality and Regulatory Director
Single Registration Number (SRN) (if available)	DE-AR-000029825

Notified body name (if applicable)	☑ See attached schedule
Notified body number (if applicable)	☑ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☑ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☑ See attached schedule
End date of extended validity/transition period	☑ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  - ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  - ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  - ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  - ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 31 Dec 2028 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  - ☐ We do not intent to lodge an application for conformity assessment by 31 Dec 2028, therefore the transition period will end on 31 Dec 2028.

  ☑ Expired/expires *after* 20 March 2023:

  Choose one applicable statement:

  ☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  - ☐ We do not intent to lodge an application for conformity assessment by 31 Dec 2028, therefore the transition period will end on 31 Dec 2028.

- **Quality Management System (QMS)**

  Choose one applicable statement:

  ☑ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 31 Dec 2028.

  ☐ A QMS in accordance with Article 10(9) MDR is in place.
  ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

  - The device(s) continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Flexicare Medical Limited

Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK.

Signature:_____ Date: 17th July 2024

Dr Gurge Phull, Regulatory / Quality Director

Email – gurge.phull@flexicare.com

Schedule of Devices –

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Suction Tubing (Sterile) 5055788700000302FH	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Drainable Bags (Sterile) 5055788700001907GY	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Leg Bags (Sterile) 5055788700001906GW	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Non-Drainable Bags (Sterile) 5055788700001908H2	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Resus Bags - Reusable 5055788700002502G9	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Resus Bags - Single Use 5055788700002501G7	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
CO2 Absorbents 5055788700002801GN	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Cannulas (Dual Nasal) 5055788700029A01L5	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Cannulas (Dual Oral Nasal) 5055788700029A02L7	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Cannulas (High Flow Nasal) 5055788700029A03L9	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Cannulas (Infant Nasal CPAP) 5055788700029A04LB	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Cannulas (Nasal) 5055788700029A05LD	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Cannulas (Nioflo) 5055788700029A07LH	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Cannulas (Pressure Relief Valve) 5055788700029A08LK	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Cannulas (Sterile Nasal) 5055788700029A06LF	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Cannulas (Veoflo) 5055788700029A09LM	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Aerosol Face Tent) 5055788700029B02LC	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Aerosol) 5055788700029B01LA	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Cluster Headache System) 5055788700029B09LS	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Dual) 5055788700029B03LE	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Oxygen Mask (Gilston T-Piece) 5055788700029B04LG	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Humidity Adaptor) 5055788700029B05LJ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Medium Concentration) 5055788700029B06LL	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Non-Sterile Non-Rebreathing) 5055788700029B07LN	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Non-Sterile Tracheostomy) 5055788700029B11LD	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Sterile Non-Rebreathing) 5055788700029B08LQ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Oxygen Mask (Sterile Tracheostomy) 5055788700029B12LF	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (T-piece Kit) 5055788700029B10LB	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Ventimask) 5055788700029B13LH	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Venturi Barrel) 5055788700029B14LK	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Venturi) 5055788700029B15LM	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Mask (Veoflo High Flow Tracheostomy Interface) 5055788700029B16LP	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Oxygen Therapy Accessories (Bubble Humidifier) 5055788700029D02LN	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Therapy Accessories (Bubble Tubing) 5055788700029D04LS	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Therapy Accessories (Corrugated Tubing) 5055788700029D05LU	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Therapy Accessories (Oxygen Tubing Connector) 5055788700029D06LW	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oxygen Therapy Accessories (Star Lumen Tubing) 5055788700029D03LQ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Oropharyngeal Airways (Sterile Guedel) 5055788700003002FP	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Oropharyngeal Airways (Williams) 5055788700003004FT	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Neonatal Resuscitation Circuits (Catheter Access Adapter) 5055788700033A01K6	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Neonatal Resuscitation Circuits (Non-Sterile) 5055788700033A02K8	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Neonatal Resuscitation Circuits (Sterile) 5055788700033A03KA	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Neonatal Resuscitation Circuits (Face Mask) 5055788700033A04KC	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Neonatal Resuscitation Units	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

5055788700033B02KD						
Urimeter 5055788700004001FU	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Filters - Electrostatic (Pulmonary Function Test Filter with Mouthpiece) 5055788700041B02KA	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Filters - Electrostatic (Non-Sterile) 5055788700041B03KC	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Filters - Electrostatic (Sterile) 5055788700041B04KE	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Filters - Mechanical (Sterile) 5055788700041C01KD	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Filters - Mechanical (Non-Sterile) 5055788700041C02KF	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Nebulisers (Maxineb Tracheostomy) 5055788700005401GP	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Nebulisers (Maxineb 90 Tracheostomy) 5055788700005402GR	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Nebulisers (Maxineb) 5055788700005403GT		07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Nebulisers (Maxineb 90) 5055788700005404GV	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Nebulisers (Large Volume Nebuliser) 5055788700005405GX	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Nebulisers (Maxineb Duo) 5055788700005406GZ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Nebulisers (Accessories) 5055788700005407H3	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Anaesthesia Circuits (Non-Sterile Argentic Corrugated) 5055788700056A01LH	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Circuits (Non-Sterile Argentic Coaxial) 5055788700056A02LK	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Circuits (Non-Sterile Argentic Flexi-Lock) 5055788700056A03LM	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Circuits (Non-Sterile Corrugated) 5055788700056A04LP	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Circuits (Non-Sterile Smoothbore) 5055788700056A05LR	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Anaesthesia Circuits (Non-Sterile Coaxial) 5055788700056A06LT	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Circuits (Non-Sterile Flexi-Lock) 5055788700056A07LV	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Circuits (Sterile Corrugated) 5055788700056A08LX	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Circuits (Sterile Smoothbore) 5055788700056A09LZ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Circuits (Sterile Coaxial) 5055788700056A10LJ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Circuits (Sterile Flexi-Lock) 5055788700056A11LL	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Circuits (Oxygen / Nitrous Oxide Circuit)	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

5055788700056A12LN						
Anaesthesia Circuits (Split Lumen) 5055788700056A13LQ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Ventilator Circuits (Sterile Corrugated) 5055788700056B07M2	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Ventilator Circuits (CPAP Mask) 5055788700056B02LQ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Ventilator Circuits (Non-Sterile Argentic Corrugated) 5055788700056B03LS	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Ventilator Circuits (Non-Sterile Corrugated) 5055788700056B04LU	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Ventilator Circuits (Non-Sterile Smoothbore)	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

5055788700056B05LW						
Ventilator Circuits (Non-Sterile Flexi-Lock) 5055788700056B06LY	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Ventilator Circuits (Sterile Smoothbore) 5055788700056B08M4	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Ventilator Circuits (Nitric Oxide) 5055788700056B09M6	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Non-Sterile Flexi-Lock Tubing) 5055788700056C15M6	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Non-Sterile Single Use Connectors)	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

5055788700056C01LT						
Breathing System Components and Accessories (Sterile Single Use Connectors) 5055788700056C02LV	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Reusable Connectors) 5055788700056C03LX	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Sterile Safety Caps) 5055788700056C04LZ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Argentic Catheter Mounts) 5055788700056C05M3	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Breathing System Components and Accessories (Non-Sterile Corrugated Catheter Mounts) 5055788700056C06M5	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Non-Sterile Smoothbore Catheter Mounts) 5055788700056C07M7	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Non-Sterile Flexi-Lock Catheter Mounts) 5055788700056C08M9	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Sterile	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Corrugated Catheter Mounts) 5055788700056C09MB						
Breathing System Components and Accessories (Sterile Smoothbore Catheter Mounts) 5055788700056C10LU	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Sterile Flexi-Lock Catheter Mounts) 5055788700056C11LW	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Non-Sterile Argentic Corrugated Tubing) 5055788700056C12LY	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Breathing System Components and Accessories (Non-Sterile Corrugated Tubing) 5055788700056C13M2	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Non-Sterile Smoothbore Tubing) 5055788700056C14M4	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Sterile Smoothbore Tubing) 5055788700056C16M8	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Capnography)	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

5055788700056C17MA						
Breathing System Components and Accessories (Exhaust Lines) 5055788700056C18MC	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Hydrophobic Disc Filters) 5055788700056C19ME	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Monitoring Lines) 5055788700056C20LX	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Mouthpieces)	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

5055788700056C21LZ						
Breathing System Components and Accessories (Spirometry Kits) 5055788700056C22M3	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (PEEP Valves) 5055788700056C23M5	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Pressure Lines) 5055788700056C24M7	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Single Use Reservoir Bags) 5055788700056C25M9	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Breathing System Components and Accessories (Reusable Reservoir Bags) 5055788700056C26MB	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Test Lungs) 5055788700056C27MD	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Valves) 5055788700056C28MF	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and Accessories (Non-Sterile Water Traps) 5055788700056C29MH	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Breathing System Components and	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Accessories (Sterile Water Traps) 5055788700056C30M2						
Breathing System Components and Accessories (Weaning T-Piece Kit) 5055788700056C31M4	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Non-Sterile Argentic Corrugated) 5055788700006001GA	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Non-Sterile Corrugated) 5055788700006002GC	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Non-Sterile Smoothbore) 5055788700006003GE	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Heated Wire Breathing Systems (Non-Sterile Corrugated & Smoothbore) 5055788700006004GG	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Non-Sterile Flexi-Lock) 5055788700006005GJ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Non-Sterile VentiMyst) 5055788700006006GL	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Sterile Argentic Corrugated) 5055788700006007GN	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Sterile Corrugated) 5055788700006008GQ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Heated Wire Breathing Systems (Sterile Smoothbore) 5055788700006009GS	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Sterile Corrugated & Smoothbore) 5055788700006010GB	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Sterile Embedded) 5055788700006011GD	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Sterile Shielded) 5055788700006012GF	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Sterile VentiMyst) 5055788700006013GH	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Heated Wire Breathing Systems (Bubble CPAP Generator) 5055788700006014GK	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Bubble CPAP System) 5055788700006015GM	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heated Wire Breathing Systems (Humidification Chambers) 5055788700006016GP	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Laryngeal Mask Airways (Reusable Silicone) 5055788700008202H4	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Laryngeal Mask Airways (Single Use Silicone) 5055788700008203H6	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Laryngeal Mask Airways (Single Use PVC) 5055788700008204H8	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Laryngeal Mask Airways (Single Use MRI) 5055788700008205HA	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Laryngeal Mask Airways (Single Use Flexi) 5055788700008206HC	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Laryngeal Mask Airways (Single Use Pro) 5055788700008207HE	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Filters - Heat and Moisture Exchangers (Sterile) 5055788700008301H7	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Filters - Heat and Moisture Exchangers (Non-Sterile) 5055788700008302H9	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heat and Moisture Exchangers (Non-Sterile Tracheostomy) 5055788700008501HH	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heat and Moisture Exchangers (Non-Sterile) 5055788700008502HK	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heat and Moisture Exchangers (Sterile Tracheostomy) 5055788700008503HM	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Heat and Moisture Exchangers (Sterile) 5055788700008504HP	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Bougies and Stylets (Bougies)	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

5055788700010801GK						
Bougies and Stylets (Stylets) 5055788700010802GM	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Video Stylets (ProVu Single Use) 5055788700109A01KU	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Silicone Foley Catheters 505578870011101KZ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Nasopharyngeal Airways (Sterile) 5055788700011401G6	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Meatal Dilators (Sterile) 5055788700011601GG	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Intermittent and Short Term Use Catheters (Hydrophillic) 5055788700011701GM	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Intermittent and Short Term Use Catheters (Lubricated) 5055788700011702GP	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Intermittent and Short Term Use Catheters (Plain) 5055788700011703GR	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Intermittent and Short Term Use Catheters (Uncoated) 5055788700011704GT	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
EZ-Flow Catheter Valves 5055788700001909H4	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Suction Catheter (Sterile) 5055788700119A01L7	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Closed Suction Catheters (with Laryngoscope)	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

5055788700119B01LC						
Closed Suction Catheters (Endotracheal) 5055788700119B02LE	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Closed Suction Catheters (Tracheostomy) 5055788700119B03LG	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
BritePro Solo Handle and Fibre Optic Blades (Blade, Sterile) 5055788700120A02JM	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
BritePro Solo Handle and Fibre Optic Blades (Handle, Sterile) 5055788700120A03JP	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
BritePro Solo Handle and Fibre Optic Blades (Laryngoscope, Sterile) 5055788700120A06JV	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

BritePro Omni (Sterile) 5055788700120C02JX	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Video Laryngoscope Handle with Blade 5055788700120E01K7	GB19/964678	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Endotracheal Tubes (Cuffed, Nasal) 505578870012301LJ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Endotracheal Tubes (Cuffed, Oral) 505578870012302LL	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Endotracheal Tubes (Cuffed, Oral/Nasal) 505578870012303LN	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Endotracheal Tubes (Cuffed, Reinforced) 505578870012307LW	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Endotracheal Tubes (Cuffed, Reinforced, with Stylet) 505578870012308LY	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Endotracheal Tubes (Uncuffed, Nasal) 505578870012304LQ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Endotracheal Tubes (Uncuffed, Oral) 505578870012305LS	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Endotracheal Tubes (Uncuffed, Oral/Nasal) 505578870012306LU	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Endotracheal Tubes (Uncuffed, Reinforced) 505578870012309M2	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Endotracheal Tubes (Uncuffed, Reinforced, with Stylet) 505578870012310LK	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Dual Guard 5055788700012402GF	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Suction Yankauer Sterile 5055788700012901H6	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

FL9000 5055788700132A02KE	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
FL9000 (Adapter Leads) 5055788700132A03KG	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
FL9000 (Temperature Probes) 5055788700132A04KJ	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Booster Heater 5055788700132C01KN	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Pocket Resuscitation Mask 5055788700014301GN	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Facemasks (Reusable) 5055788700014601H5	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Anaesthesia Facemasks (Single Use) 5055788700014602H7	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Sterile Stoma Plugs 5055788700015001GE	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Altera Breathing Circuits (Bags) 5055788700015401H2	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Altera Breathing Circuits (Circuits) 5055788700015402H4	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A
Altera Breathing Circuits (Corrugated Tubing) 5055788700015403H6	GB19/964677	07 July 2023	SGS 1639	SGS 1639	31 Dec 2028	N/A

Flexicare Medical Limited
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Registered Number: 9109193 • VAT Registration Number: GB 310 726 243

04 August 2023

Flexicare Medical Limited: Stand der Einhaltung von 2017/745 (MDR)

An alle, die es betrifft,

dieses Schreiben soll die aktuelle Position von Flexicare Medical Limited (Flexicare) in Bezug auf die Verordnung 2017/745 (die Medizinprodukteverordnung, die "MDR") in Europa klären.

Devices Classified Class I per Regulation 2017/745	**Devices Classified Class Is, Im, IIa and IIb per Regulation 2017/745**
Wie in der MDR vorgeschrieben, sind die Produkte der Klasse I von Flexicare seit dem Anwendungsdatum der MDR am 26. Mai 2021 vollständig konform.	Die Produkte der Klassen Is, Im, IIa und IIb von Flexicare unterliegen den Übergangsregelungen von Artikel 120 der MDR und sind damit konform. Dies ermöglicht Flexicare, weiterhin CE-gekennzeichnete Produkte unter dem bestehenden Zertifikat der Medizinprodukterichtlinie 93/42/EWG (MDD") rechtmäßig auf den Markt zu bringen.

Flexicare hat alle erforderlichen Schritte unternommen, um die Zertifizierung gemäß der MDR vor Ablauf unseres MDD-Zertifikats zu beantragen, einschließlich der Vorbereitung konformer technischer Unterlagen zur Überprüfung durch unsere Benannte Stelle und der Einreichung unseres Antrags im Juni 2022, mehr als ein Jahr vor Ablauf der Zertifizierung.

Aufgrund von Bedenken hinsichtlich der Kapazitäten der Benannten Stellen und der Zertifizierungsfristen sowie zur Vermeidung von Engpässen bei Medizinprodukten auf dem europäischen Markt hat das EU-Parlament kürzlich für eine Verlängerung der Übergangsregelungen nach Artikel 120 gestimmt.

Für Flexicare verlängert sich damit der Geltungsbereich der bestehenden CE-Zertifizierung vom 7. Juli 2023 bis zum 31. Dezember 2028. Flexicare erwartet daher keine Lücken in unserer CE-Zertifizierung, während wir auf unser Audit und die Zertifizierung nach MDR warten.

Unsere Benannte Stelle hat darauf hingewiesen, dass es den Benannten Stellen nach der neuen Gesetzgebung nicht gestattet ist, ein MDD-CE-Zertifikat mit verlängerten Daten neu auszustellen. Damit soll eine unnötige/übermäßige Arbeitsbelastung der Benannten Stellen vermieden werden, damit sie ihre Ressourcen auf die Durchführung von MDR-Zertifizierungsprüfungen konzentrieren können. Anstelle eines aktualisierten Zertifikats wird erwartet, dass die Benannte Stelle ein erläuterndes Schreiben ausstellen wird. Es gibt derzeit keinen Zeitrahmen, wann dieses Schreiben verfügbar sein wird, aber sobald es vorliegt, kann es bei Bedarf an Flexicare-Kunden und Aufsichtsbehörden weitergegeben werden.

Mit freundlichen Grüßen,

David Ashby

Regulatory Manager

Flexicare Medical Limited

EC Certificate Full Quality Assurance System: Certificate GB19/964677

The management system of

Flexicare Medical Ltd

Cynon Valley Business Park, Mountain Ash, CF45 4ER , UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 21 May 2021 until 07 July 2023
And remains valid subject to satisfactory surveillance audits.
Issue 8. Certified since 28 January 1997.

Certification is based on reports numbered GB/PC 05884

Authorised by

Global Medical Devices Head of Notified Body

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Flexicare Medical Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope

Sterile devices for use in anaesthesia, emergency and intensive care:
Suction catheter;
Endotracheal tubes;
Laryngeal mask airways;
Humidification chambers;
Suction Yankauers;
Infant nasal CPAP therapy device.
Foley Catheter
Short Term Use Urinary Catheter
Sterile Stoma plugs
Sterile and non-sterile devices for use in anaesthesia, emergency and intensive care:
Breathing circuits;
Humidification circuits;
Breathing filters;
Heat and moisture exchangers (HMEs);
Heat and moisture exchange (HME) filters;
Nebulisers;
Oxygen and aerosol therapy devices.
Non-sterile devices for use in anaesthesia, emergency and intensive care:
Pocket resuscitation first aid masks;
Anaesthesia facemasks;
Oxygen tubes;
Resus bag resuscitators;
Manual resuscitators;
Respiratory humidifiers;
Nebuliser compressor;
Endoscopy bite block with O2 delivery and CO2 monitoring;
Booster Heater – Respiratory Humidifier

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

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