



EU Declaration of Conformity

according to the Regulation (EU MDR) 2017/745
on Medical Devices, Annex IV.

DOC-20001b

This declaration of conformity is issued under the sole responsibility of the Legal Manufacturer:

Legal Manufacturer	 Salter Labs 30 Spur Drive El Paso, Texas 79906 USA
Manufacturer's SRN	Salter Labs – US-MF-000007934

The Legal Manufacturer hereby declares that the medical device(s) specified in this declaration meet the provision of the Regulation (EU MDR) 2017/745 on Medical Devices.

Product Line	Gas Sampling Lines See List of Devices at end of this document for specific listing.
Basic UDI	006074TF1006bETCO2GasLn8J
Device Classification	Class I, Rule 1 according to the (EU) MDR 2017/745, Annex VIII, Chapter I short-term use; Chapter III, Rule 1, non-invasive devices.

This declaration of conformity is valid until:

QMS/ISO Certification	MD 608599 – Expiry Date: 2027-03-04
Conformity Route	Route of conformity is Regulation (EU MDR) 2017/745 on Medical Devices Annex IX Quality Management System.

Signed on behalf of **Salter Labs**:

	Date of Issue:	23Jul2024
Authorized Signature and Function Printed Name: Rob Yamashita, Vice President Regulatory	Place of Issue:	Regulatory Office SUNMED LLC Grand Rapids, MI, USA

EU Declaration of Conformity

according to the Regulation (EU MDR) 2017/745
on Medical Devices, Annex IV.

DOC-20001b

Identification of Economic Operators

The Legal Manufacturer is certified by the Notified Body listed below to ISO 13485:2016 (Quality Management System) Notified Body	BSI The Netherlands Notified Body CE 2797 Say Building John M. Keynesplein 9 1066 EP Amsterdam Netherlands www.bsigroup.com
Authorized EU Representative	MT Promedt Consulting GmbH Ernst-Heckel-Straße 7 66386 St. Ingbert Germany
Authorized EU Representative SRN	MT Promedt – DE-AR-000000085

EU Declaration of Conformity

according to the Regulation (EU MDR) 2017/745
on Medical Devices, Annex IV.

DOC-20001b

List of Applied Regulations

The devices listed in this declaration are in conformity with the following EU Regulations:

Identification No.	Title
Regulation 207/2012 (eIFU)	on electronic instructions for use of medical devices
Regulation (EC) 1907/2006 (REACH)	concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) within the supply chain

List of Applied Standards

The following Common Specifications, Harmonized Standards, and/or Technical Specifications Standards have been applied to the devices in this declaration:

Identification No.	Title
BS EN ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
BS EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
BS EN ISO 14971:2019+A11:2021	Medical Devices – Application of risk management to medical devices
BS EN 62366-1:2015+A1:2020	Medical devices – Part 1: Application of usability engineering in medical devices
BS EN ISO 10993-1:2020	Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process
BS EN ISO 10993-5:2009	Biological Evaluation of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity
BS EN ISO 10993-10:2013	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization.
BS EN ISO 10993-11:2018	Biological Evaluation of Medical Devices – Part 11: Tests For Systemic Toxicity
BS EN ISO 10993-17:2009	Biological Evaluation of Medical Devices – Part 17: Establishment Of Allowable Limits For Leachable Substances
BS EN ISO 10993-18:2020	Biological Evaluation of Medical Devices – Part 18: Chemical Characterization, Extractables and Leachables, Volatile Organic Compounds
BS EN ISO 18562-1:2020	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications
BS EN ISO 18562-2:2020	Biocompatibility Evaluation Of Breathing Gas Pathways In Healthcare Applications Tests For Emissions Of Particulate Matter



EU Declaration of Conformity

DOC-20001b

*according to the Regulation (EU MDR) 2017/745
on Medical Devices, Annex IV.*

BS EN ISO 18562-3:2020	Biocompatibility Evaluation Of Breathing Gas Pathways In Healthcare Applications Tests For Emissions Of Volatile Organic Compounds
BS EN ISO 18562-4:2020	Biocompatibility Evaluation Of Breathing Gas Pathways In Healthcare Applications Tests For Leachables In Condensate
ASTM D4332-14	Environmental Conditioning Testing
ASTM D4169, DC13	Transit Testing
ASTM F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2213-17	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment



EU Declaration of Conformity

according to the Regulation (EU MDR) 2017/745
on Medical Devices, Annex IV.

DOC-20001b

Product Identification

Intended Purpose	The Gas Sampling Lines are intended to be used where exhaled gas is monitored.
Model Number of Designator	See List of Devices, below.
European Medical Device Nomenclature (EMDN) Code	Z12030685 : Vital signs monitoring consumables
Global Medical Device Nomenclature (GMDN) Code	45566 , Single use gas sample line
Universal Medical Device Nomenclature System (UMDNS) Code	11838 , gas sampling unit
Product Options/Accessories	See List of Devices, below.

List of Devices

UDI-DI	Model Number / Case QTY	Description
00607411910890	13340	CO2 Sample line (Adult), 7' (2.1m) supply tube, male Luer lock connector
00607411400001 20607411400005	4000-7 4000-7-25	Sampling (no O2) Adult Capnography Cannula, Male Luer Style. 7' Co2
00607411400018 20607411400012	4000F-7 4000F-7-25	Sampling (no O2) Adult Capnography Cannula, Female Luer Style. 7' Co2
00607411400025 20607411400029	4001-7 4001-7-25	Sampling (no O2) Adult Capnography Cannula, Male Luer Style. 7' Co2
00607411400124 20607411400128	4100-7 4100-7-25	Sampling (no O2) Pediatric Capnography Cannula, Male Luer Style. 7' Co2
00607411400131 10607411400138	4100F-7-25	Sampling (no O2) Pediatric Capnography Cannula, Female Luer Style. 7' Co2
00607411400223 20607411400227	4200-7 4200-7-25	Sampling (no O2) Infant Capnography Cannula, Male Luer Style. 7' Co2



EU Declaration of Conformity

according to the Regulation (EU MDR) 2017/745
on Medical Devices, Annex IV.

DOC-20001b

00607411400230 10607411400237	4200F-7 4200F-7-25	Sampling (no O2) Infant Capnography Cannula, Female Luer Style. 7' Co2
00607411400278 10607411400275 20607411400272	4407-7 4407-7-10 4407-7-25	CO2 Sampling Line, 1 male, 1 female luer style connector
00607411400285 10607411400282 20607411400289	4410-10 4410-10-10 4410-10-25	CO2 Sampling Line, 1 male, 1 female luer style connector
00607411400292 10607411400299	4415-15 4415-15-25	CO2 Sampling Line, 1 male, 1 female luer style connector
00607411400308 10607411400305	4430-30 4430-30-25	CO2 Sampling Line, 1 male, 1 female luer style connector
00607411400315 10607411400312 20607411400319 30607411400316	4507-7 4507-7-10 4507-7-25 4507-7-200	CO2 Sampling line, male luer style connectors
00607411400322 10607411400329 20607411400326	4510-10 4510-10-10 4510-10-25	CO2 Sampling Line, male luer style connectors
00607411400339 10607411400336	4515-15 4545-45-25	CO2 Sampling Line, male luer style connectors
00607411400346 10607411400343	4530-30 4530-30-25	CO2 Sampling Line, male luer style connectors
00607411961328 10607411961325 20607411961322	4MSF5-6 4MSF5-6-25 4MSF5-6-100	ETCO2 Filtered Sampling Line with adult/pediatric 15 mm airway adapter
00607411977916 10607411977920 20607411977934	4MSF5-6-W.1 4MSF5-6-25-W 4MSF5-6-100-W	ETCO2 Filtered Sampling Line with adult/pediatric 15 mm airway adapter
00607411963056 10607411963053	4MSF5-13 4MSF5-13-25	ETCO2 Filtered Sampling Line with adult/pediatric 15 mm airway adapter.
00607411963001 10607411963008	4MSF5-L-13 4MSF5-L-13-25	ETCO2 Filtered Sampling Line with adult/pediatric 15 mm airway adapter with Nafion moisture reduction technology



EU Declaration of Conformity

according to the Regulation (EU MDR) 2017/745
on Medical Devices, Annex IV.

DOC-20001b

00607411962998 10607411962995 20607411962992	4MSF5-L-6 4MSF5-L-6-25 4MSF5-L-6-100	ETCO2 Filtered Sampling Line with adult/pediatric 15 mm airway adapter
00607411962998 10607411977951	4MSF5-L-6-W 4MSF5-L-6-25-W	ETCO2 Filtered Sampling Line with adult/pediatric 15 mm airway adapter
00607411961120 10607411961127	4MSF8-13 4MSF8-13-25	ETCO2 Filtered Sampling Line
00607411150999 10607411150996	4MSF8-30 4MSF8-30-25	ETCO2 Filtered Sampling Line
00607411961113 10607411961110	4MSF8-6 4MSF8-6-25	ETCO2 Filtered Sampling Line
00607411961298 10607411961295	4MSF8-L-13 4MSF8-L-13-25	ETCO2 Filtered Sampling Line
00607411961281 10607411961288	4MSF8-L-6 4MSF8-L-6-25	ETCO2 Filtered Sampling Line
00607411911620	ZML-005-50	5.0 Micron Hydrophobic Filter
00607411916939 10607411916936	ZML-9021-T-1 ZML-9021-T-50	Gas Sample Line, .060" x 60," male/male luer lock connectors 5-micron hydrophobic filter, connector
00607411911637 10607411911634	ZML-9300 -1 ZML-9300-50	Gas Sample Line, .040" X 96," male/male luer lock connectors
00607411911644 10607411911641	ZML-9320-1 ZML-9320-50	Gas Sample Line, .060" X 96," male luer lock connectors
00607411916946 10607411916943	ZML-9330-1 ZML-9330-50	Gas Sample Line, .050" X 96," male/male luer lock connectors
00607411932021 10607411932028	ZML-9331-1 ZML-9331-50	Gas Sample Line, .050" X 96," 5.0 hydrophobic filter, male/male luer lock connectors
00607411916953 10607411916950	ZML-9333-1 ZML-9333-50	Gas Sample Line, .050" X 96," male/male luer lock connectors, 12" Nafion dryer tube
00607411916960 10607411916967	ZML-9340-1 ZML-9340-50	Gas Sample Line, .047" x 96," male/male luer lock connectors
00607411922084 10607411922081	ZML-9350-1 ZML-9350-50	Gas Sampling Line .040"ID x 96," male/male luer lock connectors
00607411922107 10607411922104	ZML-9420-1 ZML-9420-50	Gas Sample Line, .060" X 96," male/female luer lock connectors



EU Declaration of Conformity

according to the Regulation (EU MDR) 2017/745
on Medical Devices, Annex IV.

DOC-20001b

00607411922114 10607411922111	ZML-9430-1 ZML-9430-50	Gas Sample Line, .050" X 96," male/female luer lock connectors
00607411932038 10607411932035	ZML-9446-1 ZML-9446-50	Gas Sample Line, .047" x 96," male/female with 5.0 hydrophobic filter, 12" Nafion dryer tube
00607411911651 10607411911658	ZML-9520-1 ZML-9520-50	Gas Sample Line, .060" X 120," male luer lock connectors
00607411915376 10607411915373	ZML-9530-1 ZML-9530-50	Gas Sample Line, .050" X 120," male luer lock connectors
00607411913709 10607411913706 20607411913703	ZML-9530B-1 ZML-9530B-125 ZML-9530B-500	Gas Sample Line .050" ID x .120" OD x .120," male to male luer lock connectors
00607411915383 10607411915380	ZML-9540-1 ZML-9540-50	Gas Sample Line, .047" x 120," male to male luer lock connectors
00607411913693 10607411913690	ZML-9550-1 ZML-9550-50	Gas Sample Line, .040" x 120," male to male luer lock connectors
00607411976315 10607411976312	ZML-9600 ZML-9600-50	Gas Sample Line, .040" X 120," male to female luer lock connectors
00607411911668 10607411911665	ZML-9620-1 ZML-9620-50	Gas Sample Line, .060" X 120," male to female luer lock connectors
00607411911682 10607411911689	ZML-9630-1 ZML-9630-50	Gas Sampling Line, .050" ID x 120," 5.0u hydrophobic filter, male to female luer lock connectors
00607411952562 10607411952569	ZML-9631-1 ZML-9631-50	Gas Sample Line, .050" ID x 120," 5.0u hydrophobic filter, male to female luer lock connectors
00607411939099 10607411939096	ZML-9636-1 ZML-9636-50	Gas Sampling Line .050"ID x 120," 5.0µm hydrophobic filter, male to female luer lock connectors, 12" Nafion sample tube
10607411940436	ZML-9800-50	Gas Sampling Line, 12" Nafion sample tubes
00607411934025	ZML-9801-25	Gas Sampling Line 6" Nafion sample tubes
00607411969652	ZML-9803-4-25	Gas Sampling Line 48" Nafion sample tubes
00607411982057 10607411982054	P183291	Philips Healthcare LoFlo CO2 with Airway Adapters (989803183291)
00607411004407 10607411004404	SO-1200 SEN116	Divided Sampling (no O2) Adult Capnography Cannula, Male Luer Style. 2' Co2 (somnomedics Sen115)



EU Declaration of Conformity

according to the Regulation (EU MDR) 2017/745
on Medical Devices, Annex IV.

DOC-20001b

00607411006968 10607411006965	SO-1330 SEN116	Divided Sampling (no O2) Pediatric Capnography Cannula, Male Luer Style. 7' Co2 (somnomedics Sen116)
00607411006975 10607411006972	SO-1942 SEN116b	Divided Pediatric Capnography Cannula, Unknown. None O2 & 16" Co2 (somnomedics Sen116b)
00607411969614 10607411969611	SO-2123	Sampling (no O2) Adult Capnography Cannula, Male Luer Style. 7' CO2
00607411969621 10607411969628	SO-2124	Sampling (no O2) Pediatric Capnography Cannula, Male Luer Style. 7' CO2
00607411969638 10607411969635	SO-2125	Sampling (no O2) Infant Capnography Cannula, Male Luer Style. 7' CO2
00856038001577	1842P-25	Iradimed, Sampling Pediatric Capnography Cannula, Male Luer Style, 7' CO2, No O2
00856038001553	1842A-25	Iradimed, Sampling Adult Capnography Cannula, Male Luer Style, 7' CO2, No O2
00856038001560	1842I-25	Iradimed, Sampling Infant Capnography Cannula, Male Luer Style, 7' CO2, No O2