



Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

DECLARATION OF CONFORMITY
DOC-20017c Oxygen Tubing & Accessories

SRN: US-MF-000007934

Basic UDI: 006074TF1004_TubingZ7

Product Name:
Intended Purpose:

Model Number or Designator:
Control Designator:
Device Classification:

Conformity Route:

EMDN Nomenclature code (EMDN)
Global Medical Device Nomenclature Code (GMDN)
Universal Medical Device Nomenclature System (UMDNS)
Product Options/Accessories:
EC Certificate Number

Notified Body:

Authorized EU Representative:

Oxygen Tubing & Accessories

Oxygen tubing is a conduit to deliver oxygen from the source gas to the patient.

See the following table of part numbers

DOC-20017c 12-Sept-2022

Class IIa, Rule 2, according to the (EU) MDR 2017/745, Annex VIII, Chapter I, short-term use; Chapter III, Rule 2, Non-invasive channeling gas

Route of conformity is according to the (EU) MDR Annex IX Quality Management System

R03010204, oxygen administration tubing

12875, oxygen administration tubing

12875, oxygen administration tubing

See the following tables

MDR 738597

Expiry Date: 09-Sep-2027

BSI Group Inc.,
Notified Body CE 2797
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands
www.bsigroup.com

MT Promedt Consulting GmbH
Altenhofstasse 80
D-66386 St. Ingbert
Germany

Revision: 1

Authorized Signature and function
Printed Name: Rob Yamashita
Vice President Regulatory

Date of Issue: 12-Sep-2022
Place of Issue: Regulatory Office, SunMed
Grand Rapids, Michigan, USA

This declaration of conformity is issued under the sole responsibility of SunMed. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

All technical documentation is retained at the premises of the manufacturer/technical documentation location.



DECLARATION OF CONFORMITY
DOC-20017c Oxygen Tubing & Accessories

Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

SRN: US-MF-000007934

Basic UDI: 006074TF1004_TubingZ7

UDI	Model Number / Case Qty	Device Description
00607411001062 10607411001069	1019-100 1019-100-1	Oxygen Tubing, with 3/16" I.D. (4.8 mm), White 100' (30.5 m)
00607411919220 30607411919221	13400 13400-50	Oxygen Tubing with 2 standard connectors (6 mm), 7' (2.1 m).
00607411919237 30607411919238	13404 13404-50	Oxygen Tubing with 2 standard connectors (6 mm), 15' (4.6 m).
00607411919244 40607411919242	13407 13407-20	Oxygen Tubing with 2 standard connectors (6 mm), 30' (9.1 m).
00607411919251 30607411919252	13408 13408-50	Oxygen Tubing with 1 standard connector (6 mm) and 1 female thread grip connector, 7' (2.1 m)
00607411919268 30607411919269	13409 13409-50	Oxygen Tubing with male and female thread grip connectors 7' (2.1m)
00607411200007 10607411200004	2001-1 2001-1-50	Oxygen Tubing with 2 standard connectors, 1' (.3 m)
00607411200014 10607411200011	2002-7 2002-7-50	Oxygen Tubing with 2 standard connectors (6 mm), 7' (2.1 m)
00607411200694 10607411200691	2002G-7 2002G-7-50	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 7' (2.1 m)
00607411200021 10607411200028	2003-3 2003-3-50	Oxygen Tubing with 2 standard connectors (6 mm), 3' (0.9 m)
00607411200038 10607411200035	2004-4 2004-4-50	Oxygen Tubing with 2 standard connectors (6 mm), 3' (0.9 m)
00607411200700 10607411200707	2004G-4 2004G-4-50	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 4' (1.2 m)
00607411200076 10607411200073	2009-9 2009-9-	Oxygen Tubing with 2 standard connectors (6 mm), 9' (2.7 m)
00607411200083 10607411200080	2010-10 2010-0-50	Oxygen Tubing with 2 standard connectors (6 mm), 10' (3 m)
00607411200830 10607411200837	2010G-10 2010G-10-50	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 10' (3 m)
00607411200090 10607411200097	2012-12 2012-12-50	Oxygen Tubing with 2 standard connectors (6 mm), 12' (3.65 m)
00607411200106 10607411200103	2014-14 2014-14-50	Oxygen Tubing with 2 standard connectors (6 mm), 14' (4.3 m)
00607411200809 10607411200806	2014G-14 2014G-14-50	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 14' (4.2 m)



Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

DECLARATION OF CONFORMITY
DOC-20017c Oxygen Tubing & Accessories

SRN: US-MF-000007934

Basic UDI: 006074TF1004_TubingZ7

UDI	Model Number / Case Qty	Device Description
00607411200113 10607411200110	2015-15 2015-15-50	Oxygen Tubing with 2 standard connectors (6 mm), 15' (4.6 m)
00607411200724 10607411200721	2015G-15 2015G-15-50	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 15' (4.6 m)
00607411200137 10607411200134	2020-20 2020-20-25	Oxygen Tubing with 2 standard connectors (6 mm), 20' (6.1 m)
00607411200717 10607411200714	2020G-20 2020G-20-25	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 15' (4.6 m)
00607411200144 10607411200141	2021-21 2021-21-25	Oxygen Tubing with 2 standard connectors (6 mm), 21' (6.4 m)
00607411200731 10607411200738	2021G-21 2021G-21-25	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 21' (6.4 m)
00607411200168 10607411200165	2025-25 2025-25-25	Oxygen Tubing with 2 standard connectors (6 mm), 25' (7.6 m)
00607411200649 10607411200646	2025G-25 2025G-25-25	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 25' (7.6 m)
00607411200175 10607411200172	2030-30 2030-30-20	Oxygen Tubing with 2 standard connectors (6 mm), 30' (9.1 m)
00607411102189 10607411102186	2030G-30 2030G-30-20	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 30' (9.1 m)
00607411200182 10607411200189	2035-35 2035-35-20	Oxygen Tubing with 2 standard connectors (6 mm), 35' (10.7 m)
00607411200687 10607411200684	2035G-35 2035G-35-20	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 35' (10.7 m)
00607411200199 10607411200196	2040-40 2040-40-20	Oxygen Tubing with 2 standard connectors (6 mm), 40' (12.2 m)
00607411200670 10607411200677	2040G-40 2040G-40-20	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 40' (12.2 m)
00607411200236 10607411200233	2050-50 2050-50-50	Oxygen Tubing with 2 standard connectors (6 mm), 50' (15.2 m)
00607411200632 10607411200639	2050G-50 2050G-50-20	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 50' (15.2 m)
00607411200243 10607411200240	2075-75 2075-75-15	Oxygen Tubing with 2 standard connectors (6 mm), 75' (22.9 m)
00607411200304 10607411200301	2099-25 2099-25-50	Oxygen Tubing with 1 standard connector (6 mm) and 1 female thread grip connector, 25' (7.6 m)



DECLARATION OF CONFORMITY
DOC-20017c Oxygen Tubing & Accessories

Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

SRN: US-MF-000007934

Basic UDI: 006074TF1004_TubingZ7

UDI	Model Number / Case Qty	Device Description
00607411200748 10607411200745	2099-35 2099-35-20	Oxygen Tubing with 1 standard connector (6 mm) and 1 female thread grip connector, 35' (10.7 m)
00607411200328 10607411200325	2099-50 2099-50-20	Oxygen Tubing with 1 standard connector (6 mm) and 1 female thread grip connector, 50' (15.2 m)
00607411200335 10607411200332	2099-7 2099-7-50	Oxygen Tubing with 1 standard connector (6 mm) and 1 female thread grip connector, 7' (2.1 m)
00607411200861 10607411200868	2099G-7 2099G-7-50	Oxygen Tubing (Green) with 1 standard connector (6 mm) and 1 female thread grip connector, 7' (2.1 m)
00607411200342 10607411200349	2100-100 2100-100-10	Oxygen Tubing with 2 standard connectors (6 mm), 100' (30.5 m)
00607411200618 10607411200615	2501-1 2501-1-50	Oxygen Tubing with 2 standard connectors (6 mm), 1' (.3 m)
00607411200366 10607411200363	2503-7 2503-7-50	Oxygen Tubing with 2 standard connectors (6 mm), 7' (.2.1 m)
00607411200373 10607411200370	2504-4 2504-4-50	Oxygen Tubing with 2 standard connectors (6 mm), 4' (1.2 m)
00607411200397 10607411200394	2509-9 2509-9-50	Oxygen Tubing with 2 standard connectors (6 mm), 9' (2.7 m)
00607411200410 10607411200417	2414-14 2414-14-50	Oxygen Tubing with 2 standard connectors (6 mm), 14' (4.3 m)
00607411200427 10607411200424	2515-15 2015-15-50	Oxygen Tubing with 2 standard connectors (6 mm), 15' (4.6 m)
00607411200434 10607411200431	2520-20 2520-20-25	Oxygen Tubing with 2 standard connectors (6 mm), 20' (6.1 m)
00607411200441 10607411200448	2521-21 2521-21-25	Oxygen Tubing with 2 standard connectors (6 mm), 21' (6.4 m)
00607411200458 10607411200455	2525-25 2525-25-25	Oxygen Tubing with 2 standard connectors (6mm), 25' (7.6 m)
00607411200465 10607411200462	2530-30 2530-30-20	Oxygen Tubing with 2 standard connectors (6 mm), 30' (9.1 m)
00607411200489 10607411200486	2540-40 2540-40-20	Oxygen Tubing with 2 standard connectors (6 mm), 40' (12.2 m)
00607411200496 10607411200493	2550-50 2550-50-20	Oxygen Tubing with 2 standard connectors (6 mm), 50' (15.2 m)
00607411005480 10607411005487	9996-1 9996-1-25	Oxygen Tubing with 1 standard connector and male thread grip connector, 1' (.3 m)



Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

DECLARATION OF CONFORMITY
DOC-20017c Oxygen Tubing & Accessories

SRN: US-MF-000007934

Basic UDI: 006074TF1004_TubingZ7

UDI	Model Number / Case Qty	Device Description
00607411200526 10607411200523	9997-7 9997-7-50	Oxygen Tubing with 2 female thread grip connectors, 7' (2.1 m)
00607411200540 10607411200547	9999-7 9999-7-50	Oxygen Tubing with male and female thread grip connectors, 7' (2.1 m)
00607411200557 10607411200554	9999-14 9999-14-50	Oxygen Tubing with male and female thread grip connectors, 14' (4.2 m)
00607411200953 10607411200950	L2002-7 L2002-7-50	Oxygen Tubing with 2 standard connectors (6 mm), 7' (2.1 m)
0607411888793 1607411888794	M4150 M4150-50	OXYGEN TUBING with 2 standard connectors, 15' (4.6 m),
0607411888809 10607411888810	M4250 M4250-25	OXYGEN TUBING with 2 standard connectors, 25' (7.6 m)
0607411888823 1060741188884	M4250G M4250G-25	OXYGEN TUBING with 2 standard connectors, 25' (7.6 m), disposable
00607411915987	PRO2-2	Oxygen Tubing 3-channel with one thread grip end 2 ft (24")
00607411919510 00607411915987	R003857 R003857-25	Oxygen Tubing (Green) with 2 standard connectors (6 mm), 25' (7.6 m)
00607411200816 10607411200813	SO-676 SO-676-50	Oxygen Tubing with 1 standard connector and 1 male thread grip connector, 15" (.4m).
00607411889097 10607411889094	SO-1188 SO-1188-25	Tubing Patient Kit
00607411889103 10607411889100	SO-1189 SO-1189-50	Tubing Patient Kit
00607411889110 10607411889117	SO-1190 SO-1190-20	Tubing Patient Kit
00607411889660 10607411889667	SO-1304 SO-1304-50	Oxygen Tubing with 2 standard connectors, 40" (1.0 m)
00607411300738 10607411300735	SO-1500 SO-1500-250	Oxygen Tubing with 2 standard connectors (6 mm), 2" (5.08 Cm)
00607411010507 10607411010504 20607411010501	SO-1663 SO-1663-25 SO-1663-50	Oxygen Tubing with (1) 6 mm and (1) 8 mm connector, 2' (.61 m).
00607411801273 10607411801270	SO-1790 SO-1790-50	Oxygen Tubing with 1 standard connector and 1 male thread grip connector, 21" (.53 m).
00607411200007	SO-1943-50	Oxygen Tubing with 2 standard connectors, 1' (.3 m)
00607411005497 10607411005494	SO-1944 SO-1944-20	Oxygen Tubing with 2 standard connectors (6 mm), 50' (15.2 m)
00607411801112 10607411801119	SO-1946 SO-1946-25	Oxygen Tubing with 2 standard connectors (6 mm), 25' (7.6 m)
00607411918025 10607411918022	SO-1968 SO-1968-25	Tubing kit



DECLARATION OF CONFORMITY
DOC-20017c Oxygen Tubing & Accessories

Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

SRN: US-MF-000007934

Basic UDI: 006074TF1004_TubingZ7

UDI	Model Number / Case Qty	Device Description
00607411918070 10607411918077	SO-1972 SO-1972-25	Tubing kit
00607411961014 10607411961011	SO-2082 SO-2082-25	Oxygen Tubing with 2 standard connectors (6 mm), 25' (7.6 m)
00607411961021 10607411961028	SO-2083 SO-2083-50	Oxygen Tubing with 1 standard connector and 1 male thread grip connector, 21" (.53 m).
00607411961038 10607411961035	SO-2084 SO-2084-50	Oxygen Tubing with 2 standard connectors (6 mm), 7' (2.1 m)

Accessories

UDI	Accessory Part # / case quantity	Description of Accessory
00607411919459 30607411919450	961 961-50	Trach Tube adapter (50 per box)
20607411001097 30607411001094	1205-0-50 1205-0-500	Nipple & Nut Standard DISS 1240 oxygen fitting.
10607411969512	1205-0-50	Nipple & Nut Standard DISS 1240 oxygen fitting. (SO-2106)
10607411004909	1205C-0-50	Nipple & Nut Standard DISS 1240 oxygen fitting.
10607411001106 20607411001103	1215-0-50 1215-0-500	Oxygen Tubing connector, For attachment of additional lengths of tubing.
00607411001130 10607411001137 20607411001134 30607411001131	1220-0 1220-0-10 1220-0-25 1220-0-100	Oxygen Tubing Swivel Connector For low pressure, not to exceed 10 psi.
00607411001178 10607411001175	1222-0 1222-0-25	Oxygen Tubing Swivel Connector with clip, (delicate). For low pressure, not to exceed 10 psi.
00607411001215 10607411001212 20607411001219 30607411001216	1225-0 1225-0-10 1225-0-25 1225-0-100	Oxygen Tubing Swivel Connector For low pressure, not to exceed 689 mbar (10 psi).
00607411102165 20607411102169	1227-2-2 1227-2-2-10	Y-Connector w/2 2' Bonded Green Tubes and Ribbed End fittings
00607411102264 10607411102261	1227-7-7 1227-7-7-10	Y-Connector w/2 7' Bonded Green Tubes and Ribbed End fittings
30607411919276	13444-50	Oxygen Tubing connector, for attachment of additional lengths of tubing.
00607411919282 2060741191928 6	13445 13445-25	Oxygen Tubing Swivel Connector for low pressure, not to exceed 10 psi.
10607411200042	2005-0-50	2" Oxygen tubing connector, For attachment of additional lengths of tubing
00607411888861 10607411888868	M1220 M1220-25	Oxygen Tubing Swivel Connector For low pressure, not to exceed 10 psi.
00607411888845	M1221-25	Oxygen Tubing Swivel Connector with clip, (universal).



DECLARATION OF CONFORMITY
DOC-20017c Oxygen Tubing & Accessories

Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

SRN: US-MF-000007934

Basic UDI: 006074TF1004_TubingZ7

UDI	Accessory Part # / case quantity	Description of Accessory
00607411888847	M4610-50	NIPPLE & NUT Standard diss 1240 oxygen fitting, disposable (single patient use)
00607411888915	M4650-50	Salter Oxygen tubing connector
00607411 888885	M1523-25	Water trap, case of 25
00607411001246	7000-0	Water trap
10607411001243	7000-0-10	
00607411000966	7001-0	Water trap
10607411000963	7001-0-25	

