



DECLARATION OF CONFORMITY
DOC-20014a Oxygen Masks



Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

SRN: US-MF-000007934

Basic UDI: 006074TF1001_MasksTM

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—Full Quality Assurance System

Notified Body:

Authorized EU Representative:

Oxygen Masks

Salter Labs Oxygen Masks are intended to be used for oxygen delivery applications. They are mainly used to deliver oxygen to a spontaneous breathing patient.

See the following table of part numbers

DOC-20014a 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 gases

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

R03010201, Air/Oxygen Masks

31285, Mask, Air/Oxygen

12448, Mask, Air-Oxygen

N/A

MDR 738597

BSI Group
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands

MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7
66386 St. Ingbert
Germany

Revision: 1

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

Date of Issue: 12-Sept-2022
Place of Issue: Regulatory Office, Salter Labs
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.



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UDI #	Model Number -- Case Qty	Description
00607411800559 10607411800556	1050-7 1050-7-50	Accu-flow® Entrainment Mask (Adult), humidity cup
00607411800559 10607411301152	1102-7 1102-7-50	Oxygen Mask (Adult) Medium Concentration, 7' (2.1 m) supply tube,
00607411301186 10607411301183	1103-0 1103-0-50	Oxygen Comfort Mask (Adult) Medium Concentration
00607411801037 10607411801348 20607411801031	1114-7 1114-7-10 1114-7-50	Oxygen Mask (Infant) Medium Concentration, 7' (2.1 m) supply tube
00607411800726 10607411800723	1122-7 1122-7-50	Oxygen Mask (Pediatric) Medium Concentration, 7' (2.1 m) supply tube
00607411940651 10607411940658	1122TG-7 1122TG-7-50	Oxygen Mask (Pediatric) Medium Concentration, 7' (2.1 m) supply tube, thread grip connector
00607411800740 10607411800747	1123-0 1123-0-50	Oxygen Mask (Pediatric) Medium Concentration
00607411800757 10607411800754	1127-7 1127-7-50	Oxygen Mask (Pediatric) High Concentration Partial Rebreather, 7' (2.1 m) supply tube
00607411800764 10607411800761	1130-7 1130-7-50	Oxygen Mask (Pediatric) High concentration Non-rebreather, safety vent, 7' (2.1 m) supply tube
00607411301407 10607411301404	1130TG-7 1130TG-7-50	Oxygen Mask (Pediatric) High Concentration Non-rebreather 7 ft. tubing, thread grip connector
00607411800788 10607411800785	1140-7 1140-7-50	Oxygen Mask (Pediatric) High Concentration Non-rebreather, 7' (2.1m) supply tube
00607411919015 30607411919016	13110 13110-50	Oxygen Mask (Adult) Medium Concentration, 7' (2.1 m) supply tube
00607411919022 30607411919023	13113 13113-50	Oxygen Mask (Pediatric) Medium Concentration, 7' (2.1 m) supply tube
00607411919039 30607411919030	13120 13120-50	High Concentration partial rebreather, 7' (2.1 m) supply tube
00607411919046 30607411919047	13122 13122-50	Oxygen Mask (Adult) High Concentration Non-rebreather, safety vent, 7' (2.1 m) supply tube
00607411919053 10607411919050	13124 13124-50	Oxygen Mask (Pediatric) High Concentration, 7' (2.1m) supply tube
00607411919060 30607411919061	13125 13125-10	Oxygen Mask (Pediatric) High Concentration Non-rebreather, safety vent, 7' (2.1 m) supply tube
00607411919336 30607411919337	13815 13815-50	Percent-O2-Lock® Mask (Adult), 7' (2.1 m) supply tube
00607411800054 10607411800051	8005-7 8005-7-50	Oxygen Mask (Adult), Medium Concentration, 7' (2.1 m) supply tube,
00607411800085 10607411800082	8010-0 8010-0-50	Oxygen Mask (Adult) Medium concentration
00607411800092 10607411800099	8020-7 8020-7-50	Oxygen Mask (Adult) Medium concentration
00607411800115 10607411800112	8030-7 8030-7-50	Oxygen Mask (Adult) High concentration Non-rebreather, safety vent 7' (2.1 m) supply tube
00607411800153 10607411800150	8040-7 8040-7-50	Oxygen Mask (Adult) High Concentration Non-rebreather, 7' (2.1 m) supply tube



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00607411800191 10647411800194	8050-7 8050-7-50	Percent-O2-Lock® Mask, (Adult), 7' (2.1 m) supply tube
00607411800214 10607411800211	8054-7 8054-7-50	Percent-O2-Lock®/Trach Tee System, 7' (2.1 m) supply tube
00607411800221 10607411800228	8056-0 8056-0-50	Percent-O2-Lock® Assembly
00607411000331 10607411000338	8057-0 8057-0-50	Percent-O2-Lock® Assembly
00607411000348 10607411000345	8058-7 8058-7-50	Percent-O2-Lock® Assembly
00607411000355 10607411000352	8059-7 8059-7-50	Percent-O2-Lock® Assembly
00607411800306 10607411800303	8110-7 8110-7-50	Oxygen Mask (Adult) Medium Concentration, 7' (2.1 m) supply tube
00607411801129 10607411801126	8110-10 8110-10-25	Oxygen Mask (Adult) Medium Concentration, 7' (2.1 m) supply tube
00607411800313 10607411800310	8110TG-7 8110TG-7-50	Oxygen Mask (Adult) Medium Concentration, 7' (2.1 m) supply tube, thread grip connector
00607411891724 10607411891721	8110TLC-7 8110TLC-7-25	Oxygen Mask (Adult) Medium Concentration, 7' (2.1 m) supply tube
00607411800320 10607411800327	8115-0 8115-0-50	Oxygen Mask (Adult) Medium Concentration
00607411800337 10607411800334	8120-7 8120-7-50	High Concentration partial rebreather, 7' (2.1 m) supply tube
00607411800351 10607411800358	8121-7 8121-7-50	Percent-O2-Lock® Mask (Pediatric), 7' (2.1 m) supply tube
00607411800368 10607411800365	8121TG-7 8121TG-7-50	Percent-O2-Lock® Mask (Pediatric), 7' (2.1 m) supply tube, female thread grip connector
00607411800375 10607411800372	8125-0 8125-0-50	Oxygen Mask (Adult) High Concentration partial-rebreather, safety vents
00607411800412 10607411800419	8130-7 8130-7-50	Oxygen Mask (Adult) High concentration non-rebreather, safety vent, 7' (2.1 m) supply tube
00607411800429 10607411800426	8130-9 8130-9-25	Oxygen Mask (Adult) High Concentration non-rebreather, safety vent, 9' (2.7 m) supply tube
00607411800924 10607411800921	8130-10 8130-10-50	Oxygen Mask (Adult) High Concentration non-rebreather, safety vent, 10' (3.0 m) supply tube
00607411800382 10607411800389	8130-14 8130-14-25	Oxygen Mask (Adult) High Concentration non-rebreather, safety vent 14' (4.3 m) supply tube
00607411800436 10607411800433	8130TG-7 8130TG-7-50	Oxygen Mask (Adult) High Concentration non-rebreather, safety vent. 7' (2.1 m) supply tube, thread grip connector
00607411800443 10607411800440	8135-0 8135-0-50	Oxygen Mask (Adult) High concentration non-rebreather, safety vent
00607411800450 10607411800457	8140-7 8140-7-50	Oxygen Mask (Adult) Concentration non-rebreather, 7' (2.1 m) supply tube
00607411800467 10607411800464	8140TG-7 8140TG-7-50	Oxygen Mask (Adult) High Concentration non-rebreather, no safety vent, thread grip connector, 7' (2.1 m) supply tube



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00607411891779 10607411891776	8140TLC-7 8140TLC-7-50	Oxygen Mask (Adult) High Concentration non-rebreather, 7' (2.1 m) supply tube
00607411005718 10607411005715	8145-0 8145-0-50	Oxygen Mask (Adult) High Concentration non-rebreather
00607411800481 10607411800488	8150-7 8150-7-50	Percent-O2-Lock® Mask (Adult), 7' (2.1 m) supply tube
00607411800498 10607411800495	8150TG-7 8150TG-7-50	Percent-O2-Lock® Mask, (Adult)
00607411891786 10607411891783	8150TLC-7 8150TLC-7-25	Percent-O2-Lock® Mask (Adult), (2.1 m) supply tube.
00607411200908 10607411200905	L8110-7 L8110-7-50	Oxygen Mask (Adult) Medium Concentration, 7' (2.1 m) supply tube
00607411800900 10607411800907	SO-1111 SO-1111-30	Oxygen Mask (Adult), Medium Concentration, 7' (2.1 m) supply tube
00607411800917 10607411800914	SO-1112 SO-1112-30	Oxygen Mask (adult) High concentration partial-rebreather
00607411902932 10607411902939	SO-294 SO-294-30	Oxygen Mask (Adult) Medium Concentration, 7' (2.1 m) supply tube
00607411902963 10607411902960	SO-297 SO-297-50	Oxygen Mask (Pediatric) Medium Concentration, 7' (2.1 m) supply tube
00607411800818 10607411800815	SO-407 SO-407-50	Oxygen Mask (Adult) Medium Concentration, 7' (2.1 m) supply tube
00607411800825 10607411800822	SO-428 SO-428-30	Oxygen Mask (Adult) Medium Concentration, 7' (2.1 m) supply tube
00607411800832 10607411800839	SO-429 SO-429-30	High concentration partial rebreather, 7' (2.1 m) supply tube
00607411800849	SO-430	Oxygen Mask (Adult) High Concentration non-rebreather, safety vent, 7' (1.2 m) supply tube