



DECLARATION OF CONFORMITY
DOC-20013a Aerosol Masks

Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

SRN: US-MF-000007934

Basic UDI: '006074TF1010_AersMaskSM

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:

Aerosol Masks

Salter Labs aerosol masks are intended to be used for aerosolized medication delivery applications.

See the following table of part numbers

DOC-20013a 12-Sept-2022

Class IIa, Rule 2 according to the EU (MDR) 2017/45, Annex VIII, Chapter I short-term use; Chapter III, Rule 2 non/invasive channeling gases.

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

R03010301 Aerosol Masks and Systems

35172, Aerosol Face Mask, Non-rebreathing

12449, Masks, Air-Oxygen, Aerosol Administration

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, SunMed
Grand Rapids, Michigan, USA

This declaration of conformity is issued under the sole responsibility of Salter Labs. 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	Model Description
00607411301148 10607411301145	1100-0 1100-0-50	Aerosol Mask (Adult), elastic strap fixation
00607411800870 20607411800874	1107-0 1107-0-50	I-Guard Aerosol Mask (Pediatric), elastic strap fixation
00607411301209 10607411301206	1110-0 1110-0-50	Comfort Face Tent (Adult), elastic strap style
00607411301223 10607411301220	1112-6 1112-6-50	Comfort Face Tent, 72" large bore tubing
00607411801020 10607411801027 20607411801024	1113-0 1113-0-10 1113-0-50	Aerosol Mask (Infant), elastic strap fixation
00607411800702 10607411800709	1120-0 1120-0-50	Aerosol Mask (Pediatric), elastic strap fixation
00607411800719 10607411800716	1120-5 1120-5-50	Aerosol Mask (Pediatric), 5' (60") aerosol tubing, elastic strap fixation
00607411 918964 30607411918965	13100 13100-50	Aerosol Mask (Adult), over-the-ear fixation
00607411918988 30607411918989	13101 13101-50	Aerosol Mask (Adult), elastic strap fixation
00607411 918995 30607411918996	13102 13102-50	Aerosol Mask (Pediatric), elastic strap fixation
00607411919008 30607411919009	13103 13103-50	Comfort Face Tent (Adult), elastic strap fixation
00607411800009 10607411800006	8000-0 8000-0-50	Aerosol Mask (Adult), over-the-ear fixation
00607411800269 10607411800266	8100-0 8100-0-50	Aerosol Mask (Adult), elastic strap fixation
00607411800887 10607411800884	8107-0 8107-0-50	I-Guard Aerosol Mask (Adult), elastic strap fixation
00607411102035 10607411102032 20607411102039	8107V-0 8107V-0-10 8107V-0-50	I-Guard Aerosol Mask (Adult), elastic strap fixation
00607411890239 10607411890236	8917-0 8917-0-50	Aerosol Tee Adapter, 22 mm OD x 22 mm OD x 15 mm ID