



EU Declaration of Conformity

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

DOC-20011

Revision #: 5

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	Skin Fixation Devices See List of Devices at end of this document for specific listing.
Basic UDI-DI	006074TF1018_SkinFixY4
Device Classification	Class I, Rule 1 according to the (EU) MDR 2017/745, Annex VIII, Chapter I long-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:	04Mar2024
Authorized Signature and Function Printed Name: Rob Yamashita, Vice President Regulatory	Place of Issue:	Regulatory Office SunMed Grand Rapids, MI, USA

EU Declaration of Conformity

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

DOC-20011

Revision #: 5

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-00000008

EU Declaration of Conformity

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

DOC-20011

Revision #: 5

List of Applied Regulations

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

Identification No.	Title
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 ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
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 10993-17:2009	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
ASTM D3330/D3330M-04:2018	Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape
ASTM D4169-16, DC13	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D4332-14	Environmental Conditioning Testing



EU Declaration of Conformity

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



DOC-20011

Revision #: 5

EU Declaration of Conformity

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

DOC-20011

Revision #: 5

Product Identification

Intended Purpose	Skin fixation accessories provide a means of affixing cannula tubing to the face and body. The accessory is designed to prevent ear chafing when used with nasal cannulas or oxygen masks.
Model Number of Designator	See List of Devices, below.
European Medical Device Nomenclature (EMDN) Code	M030302 , Protection System
Global Medical Device Nomenclature (GMDN) Code	44990 , Skin-cover adhesive strip
Universal Medical Device Nomenclature System (UMDNS) Code	10028 , Adhesive strips, hypoallergenic
Product Options/Accessories	See List of Devices, below.

List of Devices

UDI-DI	Model Number / Case QTY	Description
00607411001024 10607411001021	1005-0 1005-0-25	Tender Grip, Cannula fixation device
10607411001038	1006-0-100	Tender Grip, Cannula fixation device
00607411001147 20607411001141	1007-0 1007-0-25	Tender Grip, Infant Cannula fixation device
00607411001154 20607411001158	1008-0 1008-0-25	Tender Grip, Newborn Cannula fixation device
00607411001048 10607411001045	1016-0 1016-0-50	E-Z Wrap™ Soft, closed cell foam tubes
00607411891717 10607411891714	1017-0 1017-0-25	E-Z Wrap™ Mask Cushions. Soft, closed cell foam cushions
00607411891113 10607411891110	1217-0 1217-0-25	Hydrocolloid Strips
10607411007313	MW100-0-120	Mini Whiskers securement device
10607411007344	SW102-0-25	Sticky Whiskers securement device