00063653 Rev B

MANUFACTURER'S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	Laerdal Medical AS
Business address:	P.O. Box 377, Tanke Svilandsgate 30 4002 Stavanger Norway
Medical device(s):	**Pocket Mask with Oxygen**

83000133	Pocket Mask O2 Polybag (EN)
83002133	Pocket Mask O2 SP Blue (EN)
83003133	Pocket Mask O2 HC Yellow (EN)
8301000133	Pocket Mask O2 Polybag (EN) ,10 pkg
8301002133	Pocket Mask O2 SP Blue (EN) ,10 pkg
8301003133	Pocket Mask O2 HC Yellow (EN) ,10 pkg
83019922	Pocket Mask O2 SP Black Private Label, 10 pkg
83019923	Pocket Mask O2 SP Camo Private Label, 10 pkg
83019932	Pocket Mask O2 HC White Private Label, 10 pkg
839922	Pocket Mask O2 SP Black Private Label
839923	Pocket Mask O2 SP Camo Private Label
839932	Pocket Mask O2 HC White Private Label

Classification:	Class IIa
GMDN code and term:	36066 Cardiopulmonary resuscitation mask, reusable
Scope of application:	All

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:	10000470903-PA-NoMA-DNK
Standards applied:	

AS 4259	Australian Standard. Ancillary devices for expired air resuscitation
EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23	Biological evaluation of medical devices – Part 23: Tests for Irritation
ISO 18562-1	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
ISO 18562-2	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
ISO 18562-3	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic compounds (VOCs)

ISO 18562-4	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate
ISO 5356-1	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
ISO 15223-1	Medical Devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
AS ISO 14971	Medical Devices – Application of risk Management to medical devices

Authorised signatory:

DocuSigned by:
Claudia Pajares Ibáñez
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Signature

2024-11-20

Claudia Pajares
Regulatory Affairs Manager

Date