



Laerdal
helping save lives

DECLARATION OF CONFORMITY

Responsible Manufacturer: Laerdal Medical AS
Tanke Svilandsgate 30
4007 Stavanger
Norway

Manufacturing site: (If other than mentioned above) Laerdal Medical (Suzhou), Co. Ltd.,
No.19 Building Huojo Road,
Science & Technology Industrial Park
215009 Suzhou, Jiangsu Province, P.R. China

Product Name: **Laerdal Pocket Mask (82xxxx)**

Product Options: Gloves, wipe
(w/Accessories)

to which this declaration relates is in conformity with Annex I – Essential Requirements of the **Council Directive 93/42/EEC for Medical Devices**. All supporting documentation is retained by the manufacturer.

Classification: The product is Class I according to rule 1 of Annex IX.

Class I:
Conformity Assessment is based on the principles described in Annex VII of the Directive 93/42/EEC.

Stavanger, 13 September 2006

Ole Petter Rosland
Technical Product Manager





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CONFORMITY DECLARATION - MDD


We hereby declare that "Laerdal Pocket Mask, model 8300xx and 8399xx", with accessories, manufactured by Laerdal Medical AS, p.o.box 377, N-4002 Stavanger, is manufactured in conformity with the product described in the technical file. The device is in class IIa (annex VII) according to the classification rules of annex IX.

Compliance is claimed for the essential requirements of Council directive 93/42/EEC regarding the harmonization of the memberstates' regulations regarding medical devices.

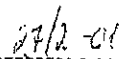
The basic product standards used are *ISO 8382:1988 Resuscitators Intended for Use With Humans* and *AS 4259-1995 Ancillary devices for expired air resuscitation*.

BSI (Notified Body no.0086) has according to the requirements of the Council directive 93/42/EEC, annex V, section 3.2, issued a certificate (CE 01638) to confirm compliance with BS EN ISO 9002 og EN 46002.

For company Laerdal Medical AS



Hilde Tertnes



Date

Laerdal Medical AS
p.o.box 377
N-4002 Stavanger

Telephone: 51511700 Fax: 51511830

MATERIAL SAFETY DATA SHEET 3M 3M Center St. Paul, Minnesota 55144-1000 (612) 733-1110

DIVISION: FILTRATION PRODUCTS TRADE NAME: FILTRETRE BRAND AIR FILTER MEDIA-Type G,GS,GSB ISSUED: August 09, 1995 SUPERSEDES: December 14, 1993 DOCUMENT: 06-0555-0

Table with 3 columns: 1. INGREDIENT, C.A.S. NO., PERCENT. Row 1: POLYPROPYLENE (STABILIZED) None 100.0

2. PHYSICAL DATA

BOILING POINT: N/A VAPOR PRESSURE: N/A VAPOR DENSITY: N/A EVAPORATION RATE: N/A SOLUBILITY IN WATER: Nil SPECIFIC GRAVITY: 910 kg/m3 PERCENT VOLATILE: N/A VOLATILE ORGANIC COMPOUNDS: N/D VOC LESS H2O & EXEMPT SOLVENTS: N/D PH: N/A VISCOSITY: N/A MELTING POINT: N/D

APPEARANCE AND ODOR: White fibrous material.

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT: N/A FLAMMABLE LIMITS - LEL: N/A FLAMMABLE LIMITS - UEL: N/A AUTOIGNITION TEMPERATURE: N/D

EXTINGUISHING MEDIA: Use carbon dioxide, alcohol foam, or dry chemical.

SPECIAL FIRE FIGHTING PROCEDURES: Fire fighters should wear self-contained breathing apparatus, operated in a positive pressure mode, when entering fires containing this or any other material.

Abbreviations: N/D - Not Determined N/A - Not Applicable

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MSDS: FILTRETE BRAND AIR FILTER MEDIA-Type G,GS,GSB
August 09, 1995

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3. FIRE AND EXPLOSION HAZARD DATA (continued)

UNUSUAL FIRE AND EXPLOSION HAZARDS:
None expected.

4. REACTIVITY DATA

STABILITY: Stable

INCOMPATIBILITY - MATERIALS/CONDITIONS TO AVOID:
None known.

HAZARDOUS POLYMERIZATION: Hazardous polymerization will not occur.

HAZARDOUS DECOMPOSITION PRODUCTS:

Thermal oxidative degradation products may include carbon monoxide,
carbon dioxide, aldehydes, ketones, hydrocarbons.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:

Pick up large pieces. Sweep up or vacuum dust.

RECOMMENDED DISPOSAL:

Landfill or incinerate, according to local regulations.

ENVIRONMENTAL DATA:

N/D

EPCRA HAZARD CLASS:

FIRE HAZARD: No PRESSURE: No REACTIVITY: No ACUTE: No CHRONIC: No

6. SUGGESTED FIRST AID

EYE CONTACT:

Flush the eye with water. Contact a physician if irritation
persists.

SKIN CONTACT:

No adverse exposure expected with normal use and handling.


INHALATION:

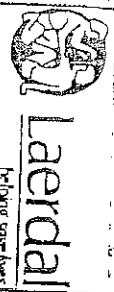
No overexposure expected with normal use and handling.

Abbreviations: N/D - Not Determined N/A - Not Applicable

Specification

3 0. 02.

| | | | | | |
|-----------------------------|---------------------------------------|---|----------------------------|--|---------------------------------------|
| LMN NO SPEC 1038 | | REV A | SHEET / OF 1 / 2 |  Laerdal <i>helping save lives</i> | POB 377 N-4001 STAVANGER NORWAY |
| FILE NAME PM spec | APPROVED BY RAD <i>[Signature]</i> | DATE 20.11.94 | | | |
| APPROVED BY N/A | DATE | APPROVED BY QA <i>[Signature]</i> | DATE 21.11.94 | THE INFORMATION CONTAINED HEREON IS PROPRIETARY TO LAERDAL AND SHALL NOT BE USED FOR ANY PURPOSE DETRIMENTAL TO OR BE REPRODUCED WITHOUT THE PERMISSION OF LAERDAL | |
| APPROVED N/A | DATE | APPROVED BY PROJECT MANAGER <i>[Signature]</i> | DATE 25.01.94 | | |
| ORIGINATOR JGr | DATE 19.01.94 | CHECKED BY VEN | DATE 2-6-94 | TITLE Pocket Mask Technical specification | |
| LANGUAGE ON THIS DOCUMENT | | REPLACES | DATE | | |
| ORIGINAL | <input checked="" type="checkbox"/> | N/A | | | |
| TRANSLATION | <input type="checkbox"/> | | | | |
| ARCHIVE | | REPLACES BY | DATE | | |
| CENTRAL | <input checked="" type="checkbox"/> | N/A | | | |
| LOCAL | <input type="checkbox"/> | | | | |
| REMARKS: | | | | | |



Pocket Mask, Spec: 1038 A

| Description | Data/requirement | Data/tested | Documentation |
|--|--------------------------------|---------------------------------|------------------|
| Flow resistance, valve: Rescuers expiratory | <5 cmH ₂ O/50 L/min | 1.6 cmH ₂ O/50 L/min | CV1023/FRD |
| Flow resistance, valve: Patient expiratory | <5 cmH ₂ O/50 L/min | 2.0 cmH ₂ O/50 L/min | CV1023/FRD |
| Flow resistance, valve: Patient inspiratory | <5 cmH ₂ O/50 L/min | 1.1 cmH ₂ O/50 L/min | CV1023/FRD |
| Flow resistance, filter: Rescuers expiratory | <5 cmH ₂ O/50 L/min | 3.0 cmH ₂ O/50 L/min | FILTER11.DOC |
| Flow resistance, filter: Patient expiratory | <5 cmH ₂ O/50 L/min | 3.4 cmH ₂ O/50 L/min | FILTER11.DOC |
| Flow resistance, filter: Patient inspiratory | <5 cmH ₂ O/50 L/min | 3.5 cmH ₂ O/50 L/min | FILTER11.DOC |
| Flow resistance, pocket mask: Rescuers expiratory | <5 cmH ₂ O/50 L/min | 0.8 cmH ₂ O/50 L/min | CV1023/FRD |
| Flow resistance, pocket mask: Patient expiratory | <5 cmH ₂ O/50 L/min | 1.6 cmH ₂ O/50 L/min | CV1023/FRD |
| Flow resistance, valve, pocket mask: Rescuers expiratory | <5 cmH ₂ O/50 L/min | 2.3 cmH ₂ O/50 L/min | CV1023/FRD |
| Flow resistance, valve, pocket mask: Patient expiratory | <5 cmH ₂ O/50 L/min | 3.2 cmH ₂ O/50 L/min | CV1023/FRD |
| Flow resistance, valve, pocket mask: Patient inspiratory | <5 cmH ₂ O/50 L/min | 2.1 cmH ₂ O/50 L/min | CV1023/FRD |
| Flow resistance, filter, pocket mask: Rescuers expiratory | <5 cmH ₂ O/50 L/min | 3.4 cmH ₂ O/50 L/min | FILTER11.DOC |
| Flow resistance, filter, pocket mask: Patient expiratory | <5 cmH ₂ O/50 L/min | 4.5 cmH ₂ O/50 L/min | FILTER11.DOC |
| Flow resistance, filter, pocket mask: Patient inspiratory | <5 cmH ₂ O/50 L/min | 3.9 cmH ₂ O/50 L/min | FILTER11.DOC |
| Flow resistance, valve, filter, pocket mask: Rescuers expiratory | <8 cmH ₂ O/50 L/min | 4.6 cmH ₂ O/50 L/min | PMTEST11.DOC/FRD |
| Flow resistance, valve, filter, pocket mask: Patient expiratory | <8 cmH ₂ O/50 L/min | 5.5 cmH ₂ O/50 L/min | PMTEST11.DOC/FRD |
| Flow resistance, valve, filter, pocket mask: Patient inspiratory | <8 cmH ₂ O/50 L/min | 4.3 cmH ₂ O/50 L/min | PMTEST11.DOC/FRD |
| Forward leakage: Tidal volume 800 mL | | 68 mL | CV1023 |
| Forward leakage: Tidal volume 100 mL | | 39 mL | CV1023 |
| Requirement for use | | | PUKETST1.DOC |

Note: Patient may not exhale freely when rescuers port is fully or partially blocked