



Laerdal

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00074244 Rev B

EU Medical Device Procedure Pack Statement of Compatibility

**Responsible
Procedure Pack
Producer** Laerdal Medical AS
P.O. Box 377
Tanke Svilandsgate 30
4002 Stavanger
Norway

**Single Registration
Number (SRN):** NO-PR-000002650

**Procedure Pack
Producer site:** Laerdal Medical (Suzhou) Co. Ltd.
Building 18, 19, 20, No.57 Huoju Road,
Science & Technology Industrial Park,
Suzhou, Jiangsu Province 215009,
China

Procedure Pack Pocket Mask with Gloves and Wipe
(full list of Catalogue Numbers overleaf)

Basic UDI-DI: 0704543209950SX

The Procedure Pack to which this declaration relates is contains the following medical devices and products

Catalogue Number:	Name:	UDI-DI:
820000	Pocket Mask	07045432106015
7235L	Nitrile Examination Powder-free Gloves	06930518033044
2122	Hand Wipe	N/A

The Pocket Mask, Examination Gloves and the Hand Wipe included in the procedure pack has been verified to be mutually compatible when used in accordance with the manufacturers' instructions.

The procedure pack incorporates the information supplied by the manufacturers of the Pocket Mask, Examination Gloves and the Hand Wipe.

The procedure pack has been combined in conformance with the applicable processes of the Laerdal ISO 13485 certified Quality Management System.

This statement has been drawn up as defined in EU Regulation 2017/745, Article 22

Mari Kaada

Mari Kaada
Corporate Director Q&R
On behalf of CEO, Alf Christian Dybdahl
10.01.2022
Stavanger, Norway

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Catalogue Number	Name
82000733	Pocket Mask w/strap HC (IE)
82001104	Pocket Mask HC (NL)
82001105	Pocket Mask HC (J)
82001107	Pocket Mask HC (F)
82001110	Pocket Mask HC(D)
82001133	Pocket Mask HC (IE)
82101133	Pocket Mask HC (IE), 100 pkg
82004000	Pocket Mask, SP (Blue, N)
82004002	Pocket Mask, SP (Blue, S)
82004004	Pocket Mask, SP (Blue, NL)
82004005	Pocket Mask, SP (Blue, J)
82004007	Pocket Mask, SP (Blue, F)
82004008	Pocket Mask, SP (Blue, SF)
82004010	Pocket Mask, SP (Blue, D)
82004011	Pocket Mask, SP (Blue, DK)
82004033	Pocket Mask, SP (Blue, IE)
82104033	Pocket Mask,SP (Blue,IE), 100 pkg
82004100	Pocket Mask, SP (Black, N)
82004102	Pocket Mask, SP (Black, S)
82004104	Pocket Mask, SP (Black, NL)
82004105	Pocket Mask, SP (black, J)
82004107	Pocket Mask, SP (Black, F)
82004110	Pocket Mask, SP (Black, D)
82004111	Pocket Mask, SP (Black, DK)
82004133	Pocket Mask, SP (Black, IE)
82004143	Pocket Mask, SP (Black, PL)
82004205	Pocket Mask, SP (Camouflage, J)
82004207	Pocket Mask, SP (Camouflage, F)
82004210	Pocket Mask, SP (Camouflage, D)
82004233	Pocket Mask, SP (Camouflage, IE)
82990911	Pocket Mask, SP (Falck, DK)
829911	Pocket Mask, HC, PL
82109911	Pocket Mask HC, PL 100 pkg
82109940	Pocket Mask SP, PL, 100 pkg
82994005	Pocket Mask, SP, PL w/o wipes (J)
829951	Pocket Mask HC, PL green
82109951	Pocket Mask HC, PL green, 100 pkg
829952	Pocket Mask, HC, PL
820012	Pocket Mask w/gloves ARC stock no.329705
82100012	Pocket Mask w/gloves ARC stock no.329705, 100 pkg



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820015	Pocket Mask, SP (ARC)
82100015	Pocket Mask, SP (ARC), 100 pkg
820023	Pocket Mask HC, Implox
820024	Pocket Mask HC, RLSSA
820025	Pocket Mask HC, St John
820032	Pocket Mask HC PL no
82104133	Pocket Mask, SP (Black, IE), 100 pkg
82104233	Pocket Mask, SP (Camouflage IE), 100 pkg

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PRO-RP01-1150 Rev M

EU DECLARATION OF CONFORMITY

Responsible Manufacturer: Laerdal Medical AS
P.O. Box 377
Tanke Svilandsgate 30
4002 Stavanger
Norway

Single Registration Number (SRN): NO-MF-000000012

Manufacturing site: Laerdal Medical (Suzhou) Co., Ltd.
Building 18,19,20, No. 57 Huoju Road
Science & Technology Industrial Park
Suzhou, Jiangsu Province 215009
China

Product Name: Laerdal Pocket Mask

Basic UDI-DI: 0704543209939TB

Intended Purpose: Intended for mouth-to-mask ventilation of a non-breathing adult, child or infant as a barrier between the rescuer and patient

Product Options:

820000 Pocket Mask
82000600 Pocket Mask, PB (N)
82000602 Pocket Mask, PB (S)
82000604 Pocket Mask, PB (NL)
82000605 Pocket Mask, PB (J)
82000610 Pocket Mask, PB (D)
82000633 Pocket Mask, PB (IE)
82100633 Pocket Mask, PB(IE), 100 pkg
82001926 Pocket Mask w/o wipe & gloves HC (CN)
82001933 Pocket Mask w/o wipe & gloves HC (IE)
82101933 Pocket Mask w/o wipe & gloves HC (IE), 100 pkg

820044 Dynamed CPR Mask, White
82100044 Dynamed CPR Mask White, 100 pkg
820045 Dynamed CPR Mask, Green
82100045 Dynamed CPR Mask Green, 100 pkg
820046 Moore Medical CPR Mask, Barrier Dev. 73508
82100046 Moore Medical CPR Mask, Barrier Dev.73508,100pkg

to which this declaration relates is in conformity with the General Safety and Performance Requirements of EU Regulation 2017/745

Classification: The Laerdal Pocket Mask is class I according to rules 1 and 4 of Annex VIII of the EU Medical Device Regulation.

Conformity Assessment is based on the principles described in Article 52 of Regulation 2017/745

Conformity is declared in relation to common Specification(s):

No CS for mouth-to-mask ventilation masks published at this time

This EU Declaration of Conformity is issued under the sole responsibility of Laerdal Medical AS.

DocuSigned by:
Mari Kaada
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Mari Kaada

Corporate Director Q&R

On behalf of Alf Christian Dybdahl, CEO

10.01.2022

Stavanger, Norway

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