



EU Medical Device Procedure Pack

Statement of Compatibility

Responsible Laerdal Medical AS
Procedure Pack P.O. Box 377
Producer Tanke Svilandsgate 30
4002 Stavanger
Norway
Single Registration NO-PR-000002650
Number (SRN):
Procedure Pack Laerdal Medical (Suzhou) Co. Ltd.
Producer site: 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



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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00074244 Rev B

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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