



# EU DECLARATION OF CONFORMITY

<b>Responsible Manufacturer:</b>	Laerdal Medical AS P.O. Box 377 Tanke Svilandsgate 30 4002 Stavanger Norway
<b>Single Registration Number (SRN):</b>	NO-MF-000000012
<b>Manufacturing site:</b>	Laerdal Medical (Suzhou) Co., Ltd. Building 18,19,20, No. 57 Huoju Road Science & Technology Industrial Park Suzhou, Jiangsu Province 215009 China
<b>Product Name:</b>	Laerdal Pocket Mask
<b>Basic UDI-DI:</b>	0704543209939TB
<b>Intended Purpose:</b>	Intended for mouth-to-mask ventilation of a non-breathing adult as a barrier between the rescuer and patient.
<b>Product Options:</b>	
82000100	Pocket Mask, PB (NO SV FI DA)
82000104	Pocket Mask, PB (NL PL FR DE)
82000110	Pocket Mask, PB (DE FR ES IT EN)
82000133	Pocket Mask, PB (EN)
82002100	Pocket Mask, SP Blue (NO SV FI DA)
82002104	Pocket Mask, SP Blue (NL PL FR DE)
82002110	Pocket Mask, SP Blue (DE FR ES IT EN)
82002133	Pocket Mask, SP Blue (EN)
82003100	Pocket Mask, HC Yellow (NO SV FI DA)
82003104	Pocket Mask, HC Yellow (NL PL FR DE)
82003110	Pocket Mask, HC Yellow (DE FR ES IT EN)
82003133	Pocket Mask, HC Yellow (EN)
829932	Pocket Mask, HC White Private Label
829922	Pocket Mask, SP Black Private Label
829923	Pocket Mask, SP Camo Private Label
82990911	Pocket Mask, SP Falck (DK)
8201000100	Pocket Mask, PB (NO SV FI DA) ,10 pkg
8201000104	Pocket Mask, PB (NL PL FR DE) ,10 pkg
8201000110	Pocket Mask, PB (DE FR ES IT EN) ,10 pkg
8201000133	Pocket Mask, PB (EN) ,10 pkg
8201002100	Pocket Mask, SP Blue (NO SV FI DA) ,10 pkg
8201002104	Pocket Mask, SP Blue (NL PL FR DE) ,10 pkg
8201002110	Pocket Mask, SP Blue (DE FR ES IT EN) ,10 pkg
8201002133	Pocket Mask, SP Blue (EN) ,10 pkg
8201003100	Pocket Mask, HC Yellow (NO SV FI DA) ,10 pkg
8201003104	Pocket Mask, HC Yellow (NL PL FR DE) ,10 pkg
8201003110	Pocket Mask, HC Yellow (DE FR ES IT EN) ,10 pkg
8201003133	Pocket Mask, HC Yellow (EN) ,10 pkg
82019932	Pocket Mask, HC White Private Label, 10 pkg
82019922	Pocket Mask, SP Black Private Label, 10 pkg
82019923	Pocket Mask, SP Camo Private Label, 10 pkg



8201990911

Pocket Mask, SP Falck (DK), 10 pkg

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 rule 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:

  
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Claudia Pajares Ibanez

Regulatory Affairs Manager

On behalf of Alf Christian Dybdahl, CEO

11 February 2025

Stavanger, Norway