00088944 Rev A

# EU DECLARATION OF CONFORMITY

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|---|---|
| **Responsible Manufacturer:** | Laerdal Medical AS<br>P.O. Box 377<br>Tanke Svilandsgate 30<br>4002 Stavanger<br>Norway |
| **Single Registration Number:** | NO-MF-000000012 |
| **Manufacturing site:** | Laerdal Medical (Suzhou) Co., Ltd.<br>Building 18,19,20, No. 57 Huoju Road<br>Science & Technology Industrial Park<br>Suzhou, Jiangsu Province 215009<br>China |
| **Product Name:** | The BAG Mask |
| **Basic UDI-DI:** | 0704543209969TL |
| **Intended Purpose:** | The BAG Mask is intended to be used for ventilation of patients |

**Product Options:**

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|---|---|---|
| 847011 | The BAG Mask #1 | 12 pack |
| 847012 | The BAG Mask #2 | 12 pack |
| 847013 | The BAG Mask #3 | 12 pack |
| 847014 | The BAG Mask #4 | 12 pack |
| 847015 | The BAG Mask #5 | 12 pack |
| 8470111 | The BAG Mask #1 | 1 pack |
| 8470121 | The BAG Mask #2 | 1 pack |
| 8470131 | The BAG Mask #3 | 1 pack |
| 8470141 | The BAG Mask #4 | 1 pack |
| 8470151 | The BAG Mask #5 | 1 pack |
| 8470110 | The BAG Mask #1 | Single unit |
| 8470120 | The BAG Mask #2 | Single unit |
| 8470130 | The BAG Mask #3 | Single unit |
| 8470140 | The BAG Mask #4 | Single unit |
| 8470150 | The BAG Mask #5 | Single unit |

**Medical Device Accessories:** None

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

**Classification:**

The BAG Mask is class IIa according to rule 2 of Annex VIII of the EU Medical Device Regulation.

Conformity Assessment is based on the principles described in Article 52 and Annex IX, Chapters I and III, including Section 4 of Regulation 2017/745.

**Conformity is declared in relation to common Specification(s):**
*No Common Specification for ventilation devices published at this time.*

Conformity with the procedures laid out in Article 52 and Annex IX, Chapters I and III has been assessed by DNV Product Assurance AS with Notified Body number 2460, Certificate number 10000470902-PA-NoMA-DNK.

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

Adrienne Farrington

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Adrienne Farrington
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Regulatory Affairs Specialist
On behalf of Alf Christian Dybdhal, CEO
19th March 2025
Stavanger, Norway