



# EU DECLARATION OF CONFORMITY

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|------------------------------------|--|----------------------------------|---------|
| <b>Responsible Manufacturer:</b>   | Laerdal Medical AS<br>P.O. Box 377<br>Tanke Svilandsgate 30<br>4002 Stavanger<br>Norway  |                                  |         |
| <b>Single Registration Number:</b> | NO-MF-000000012  |                                  |         |
| <b>Manufacturing site:</b>         | 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 |                                  |         |
| <b>Product Name:</b>               | The BAG  |                                  |         |
| <b>Basic UDI-DI:</b>               | 0704543209943T2  |                                  |         |
| <b>Intended Purpose:</b>           | The BAG Resuscitator provides positive pressure ventilation and allows spontaneous breathing with a face mask or an advanced airway.                           |                                  |         |
| <b>Product Options:</b>            | 847100   | The BAG Newborn                  |         |
|                                    | 847200   | The BAG Pediatric                |         |
|                                    | 847300   | The BAG Adult                    |         |
| <b>Medical Device Accessories:</b> | 847021   | The BAG PEEP Valve 2-10 cmH2O    | 12 pack |
|                                    | 847022   | The BAG PEEP Valve 5-20 cmH2O    | 12 pack |
|                                    | 847030   | The BAG Breathing Filter         | 12 pack |
|                                    | 847040   | The BAG Manometer                | 12 pack |
|                                    | 847050   | The BAG Bag Refill Valve Adapter | 12 pack |
|                                    | 8470211  | The BAG PEEP Valve 2-10 cmH2O    | 1 pack  |
|                                    | 8470221  | The BAG PEEP Valve 5-20 cmH2O    | 1 pack  |
|                                    | 8470301  | The BAG Breathing Filter         | 1 pack  |
|                                    | 8470401  | The BAG Manometer                | 1 pack  |
|                                    | 8470501  | The BAG Bag Refill Valve Adapter | 1 pack  |

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

## Classification:

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

Accessories are 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.



**Laerdal**  
helping save lives

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

DocuSigned by:  
*Adrienne Farrington*  
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Adrienne Farrington

Regulatory Affairs Specialist

On behalf of Alf Christian Dybdahl, CEO

29<sup>th</sup> April 2025

Stavanger, Norway