



EU DECLARATION OF CONFORMITY

Responsible Manufacturer:	Laerdal Medical AS P.O. Box 377 Tanke Svilandsgate 30 4002 Stavanger Norway		
Single Registration Number:	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:	The BAG		
Basic UDI-DI:	0704543209943T2		
Intended Purpose:	The BAG Resuscitator provides positive pressure ventilation and allows spontaneous breathing with a face mask or an advanced airway.		
Product Options:	847100	The BAG Newborn	
	847200	The BAG Pediatric	
	847300	The BAG Adult	
Medical Device Accessories:	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
29th April 2025
Stavanger, Norway