

# DECLARATION OF CONFORMITY

**Responsible Manufacturer:** Laerdal Medical AS  
P.O. Box 377  
Tanke Svilandsgate 30  
4002 Stavanger  
Norway

**Manufacturing site: (If other than mentioned above)** Polymed (Xiamen) Plastic Industrial Co., Ltd.  
Unit B, 1~5 F, Warehouse & Process Complex Building Xiangyu F.T.Z., Xiamen, China

**Product Name:** **Laerdal Disposable Resuscitator**

**Product Options:**

845011	The BAG II Disposable Resuscitator Adult w/mask #5
845041	The BAG II Disposable Resuscitator Adult w/mask #4
845021	The BAG II Disposable Resuscitator Child w/mask #3
845023	The BAG II Disposable Resuscitator Child w/mask #2
845031	The BAG II Disposable Resuscitator Infant w/mask #1
845051	The BAG II Disposable Resuscitator Adult w/mask #5 w/inflation port
845052	The BAG II Disposable Resuscitator Child w/mask #3 w/inflation port

845111	The BAG II Resuscitator Adult w/mask #5
845141	The BAG II Resuscitator Adult w/mask #4
845151	The BAG II Resuscitator Adult mask #5 w/inf.port
845152	The BAG II Resuscitator Child mask #3 w/inf.port
845121	The BAG II Resuscitator Child w/mask #3
845123	The BAG II Resuscitator Child w/mask #2
845131	The BAG II Resuscitator Infant w/mask #1

845211	The BAG II Resuscitator Adult w/mask #5
845241	The BAG II Resuscitator Adult w/mask #4
845251	The BAG II Resuscitator Adult mask #5 w/inf.port
845252	The BAG II Resuscitator Child mask #3 w/inf.port
845221	The BAG II Resuscitator Child w/mask #3
845223	The BAG II Resuscitator Child w/mask #2
845231	The BAG II Resuscitator Infant w/mask #1

**Accessories**                    845040    Laerdal Disposable PEEP Valve Assembly (5-20 cm H<sub>2</sub>O) (qty. 10)

to which this declaration relates is in conformity with  
**Essential Requirements of the Council Directive 93/42/EEC for Medical Devices, as amended by 20017/47/EC.** All supporting documentation is retained by the manufacturer.

**Classification:**                The product is Class IIa according to rule 2 of Annex IX.

Laerdal Medical AS is certified by Det Norske Veritas, DNV, to EN ISO13485:2012. Conformity Assessment is based on the principles described in Annex II of the Directive 93/42/EEC, minus Section 4.

**Stavanger, 3rd March 2016**

*Claudia Pajares*

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**Regulatory Affairs**

**CE** 0434