

EU DECLARATION OF CONFORMITY

Responsible Manufacturer:	Laerdal Medical AS P.O. Box 377 Tanke Svilandsgate 30 4002 Stavanger Norway		
Manufacturing site:	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:	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	
	84511105	The BAG II Resuscitator Adult w/mask #5	
	84514105	The BAG II Resuscitator Adult w/mask #4	
	84515105	The BAG II Resuscitator Adult mask #5 w/inf.port	
	84515205	The BAG II Resuscitator Child mask #3 w/inf.port	
	84512105	The BAG II Resuscitator Child w/mask #3	
	84512305	The BAG II Resuscitator Child w/mask #2	
	84513105	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	
	84521105	The BAG II Resuscitator Adult w/mask #5	
	84524105	The BAG II Resuscitator Adult w/mask #4	
	84525105	The BAG II Resuscitator Adult mask #5 w/inf.port	
	84525205	The BAG II Resuscitator Child mask #3 w/inf.port	
	84522105	The BAG II Resuscitator Child w/mask #3	
	84522305	The BAG II Resuscitator Child w/mask #2	
	84523105	The BAG II Resuscitator Infant w/mask #1	
Accessories:	845140	Laerdal Disposable PEEP valve assembly	
	845155	Laerdal Disp. Mask #1 w/inflation port	
	845156	Laerdal Disp. Mask #2 w/inflation port	
	845150	Laerdal Disp. Mask #3 w/inflation port	
	845160	Laerdal Disp. Mask #4 w/inflation port	
	845170	Laerdal Disp. Mask #5 w/inflation port	
	84514005	Laerdal Disposable PEEP valve assembly	
	84515505	Laerdal Disp. Mask #1 w/inflation port	
	84515605	Laerdal Disp. Mask #2 w/inflation port	
	84515005	Laerdal Disp. Mask #3 w/inflation port	
	84516005	Laerdal Disp. Mask #4 w/inflation port	
	84517005	Laerdal Disp. Mask #5 w/inflation port	



845240	Laerdal Disposable PEEP Valve Assembly, pkg 10
845255	Laerdal Disp. Mask #1 w/inflation port, pkg 20
845256	Laerdal Disp. Mask #2 w/inflation port, pkg 20
845250	Laerdal Disp. Mask #3 w/inflation port, pkg 20
845260	Laerdal Disp. Mask #4 w/inflation port, pkg 20
845270	Laerdal Disp. Mask #5 w/inflation port, pkg 20

84524005	Laerdal Disposable PEEP Valve Assembly, pkg 10
84525505	Laerdal Disp. Mask #1 w/inflation port, pkg 20
84525605	Laerdal Disp. Mask #2 w/inflation port, pkg 20
84525005	Laerdal Disp. Mask #3 w/inflation port, pkg 20
84526005	Laerdal Disp. Mask #4 w/inflation port, pkg 20
84527005	Laerdal Disp. Mask #5 w/inflation port, pkg 20

to which this declaration relates is in conformity with

Essential Requirements of the Council Directive 93/42/EEC for Medical Devices, as amended by 2007/47/EC.

All supporting documentation is retained by the manufacturer.

Classification:

The products The BAG II Resuscitator, Laerdal Disposable PEEP Valve Assembly and the Laerdal disposable masks with inflation port are Class IIa according to rule 2 of Annex IX.

Laerdal Medical AS is certified by DNV GL Nemko Presafe AS to ISO13485:2016. Conformity Assessment is based on the principles described in Article 11.2.b and Annex V (Module D1) of Directive 93/42/EEC.

Stavanger, 2 November 2021

Corporate Director Q&R
on behalf of Alf Christian Dybdahl, CEO

