



## EU DECLARATION OF CONFORMITY

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<b>Responsible Manufacturer:</b>	Laerdal Medical AS P.O. Box 377 Tanke Svilandsgate 30 4002 Stavanger Norway																																																								
<b>Manufacturing site:</b>	Polymed (Xiamen) Plastic Industrial Co., Ltd. Unit B, 1~5 F, Warehouse & Process Complex Building Xiangyu F.T.Z., Xiamen, China																																																								
<b>Product Name:</b>	<b>Laerdal Disposable Resuscitator</b>																																																								
<b>Product Options:</b>	<table><tr><td>845111</td><td>The BAG II Resuscitator Adult w/mask #5</td></tr><tr><td>845141</td><td>The BAG II Resuscitator Adult w/mask #4</td></tr><tr><td>845151</td><td>The BAG II Resuscitator Adult mask #5 w/inf.port</td></tr><tr><td>845152</td><td>The BAG II Resuscitator Child mask #3 w/inf.port</td></tr><tr><td>845121</td><td>The BAG II Resuscitator Child w/mask #3</td></tr><tr><td>845123</td><td>The BAG II Resuscitator Child w/mask #2</td></tr><tr><td>845131</td><td>The BAG II Resuscitator Infant w/mask #1</td></tr><tr><td>84511105</td><td>The BAG II Resuscitator Adult w/mask #5</td></tr><tr><td>84514105</td><td>The BAG II Resuscitator Adult w/mask #4</td></tr><tr><td>84515105</td><td>The BAG II Resuscitator Adult mask #5 w/inf.port</td></tr><tr><td>84515205</td><td>The BAG II Resuscitator Child mask #3 w/inf.port</td></tr><tr><td>84512105</td><td>The BAG II Resuscitator Child w/mask #3</td></tr><tr><td>84512305</td><td>The BAG II Resuscitator Child w/mask #2</td></tr><tr><td>84513105</td><td>The BAG II Resuscitator Infant w/mask #1</td></tr><tr><td>845211</td><td>The BAG II Resuscitator Adult w/mask #5</td></tr><tr><td>845241</td><td>The BAG II Resuscitator Adult w/mask #4</td></tr><tr><td>845251</td><td>The BAG II Resuscitator Adult mask #5 w/inf.port</td></tr><tr><td>845252</td><td>The BAG II Resuscitator Child mask #3 w/inf.port</td></tr><tr><td>845221</td><td>The BAG II Resuscitator Child w/mask #3</td></tr><tr><td>845223</td><td>The BAG II Resuscitator Child w/mask #2</td></tr><tr><td>845231</td><td>The BAG II Resuscitator Infant w/mask #1</td></tr><tr><td>84521105</td><td>The BAG II Resuscitator Adult w/mask #5</td></tr><tr><td>84524105</td><td>The BAG II Resuscitator Adult w/mask #4</td></tr><tr><td>84525105</td><td>The BAG II Resuscitator Adult mask #5 w/inf.port</td></tr><tr><td>84525205</td><td>The BAG II Resuscitator Child mask #3 w/inf.port</td></tr><tr><td>84522105</td><td>The BAG II Resuscitator Child w/mask #3</td></tr><tr><td>84522305</td><td>The BAG II Resuscitator Child w/mask #2</td></tr><tr><td>84523105</td><td>The BAG II Resuscitator Infant w/mask #1</td></tr></table>	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
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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**



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

