

**Laerdal**

helping save lives

PRO-RP01-0266 Rev N

# EU DECLARATION OF CONFORMITY

<b>Responsible Manufacturer:</b>	Laerdal Medical AS P.O. Box 377 Tanke Svilandsgate 30 4002 Stavanger Norway	
<b>Single Registration Number (SRN):</b>	NO-MF-000000012	
<b>Manufacturing site:</b>	Formed Plastics, Inc. 207 Stonehinge Lane Carle Place, NY 11514, USA	
<b>Product Name:</b>	BaXstrap	
<b>Basic UDI-DI:</b>	0704543209937T7	
<b>Intended Purpose:</b>	A base structure to be used with other adjunct cervical spine and head immobilization devices to facilitate in-line, neutral immobilization and transport of adult and paediatric patients.  SpeedBlocks and PadPack are accessories intended to stabilize the patient's head from lateral, flexion and extension movement.  BaXstrap and its accessories should be used in conjunction with a cervical collar and head immobilization devices to prevent secondary spinal cord injuries.	
<b>Product Options:</b>	982500	BaXstrap Spineboard
	982599	BaXstrap Spineboard, Private Label
	982600	BaXstrap Spineboard, Green
	982699	BaXstrap Spineboard, Green, Private Label
<b>Accessories:</b>	980800	BaXstrap Carry Bag
	983090	SpeedBlocks Starter Pack, (Qty.1)
	982100	PadPack Alignment pads

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

**Classification:** BaXstrap and its accessories are class I according to rule 1 of Annex VIII of the EU Medical Device Regulation.

Laerdal Medical AS is certified by DNV GL Presafe AS to ISO 13485: 2016.

Conformity Assessment is based on the principles described in Article 52 of Regulation 2017/745

**Conformity is declared in relation to common Specification(s):**

*No CS available at this time*

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

DocuSigned by:

*Valentina Langa***Valentina Langa**

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**Regulatory Affairs Specialist  
on behalf of Alf Christian Dybdahl, CEO**



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