EU DECLARATION OF CONFORMITY

Responsible Manufacturer:	Laerdal Medical AS P.O. Box 377 Tanke Svilandsgate 30 4002 Stavanger Norway
Single Registration Number (SRN):	NO-MF-000000012
Manufacturing site:	Formed Plastics, Inc. 207 Stonehinge Lane Carle Place, NY 11514, USA
Product Name:	BaXstrap
Basic UDI-DI:	0704543209937T7
Intended Purpose:	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.

Product Options:	982500	BaXstrap Spineboard
	982599	BaXstrap Spineboard, Private Label
	982600	BaXstrap Spineboard, Green
	982699	BaXstrap Spineboard, Green, Private Label
Accessories:	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
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Valentina Langa
Regulatory Affairs Specialist
on behalf of Alf Christian Dybdahl, CEO

CE

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