



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 for BaXstrap: Formed Plastics, Inc.
207 Stonehinge Lane
Carle Place, NY 11514, USA

Manufacturing site for SpeedBlocks: G&F Industries
PO Box 515, route 20
Sturbridge, MA 0156, USA

Manufacturing site for PadPack: Rogers Foam Tijuana
Blvd. Paseo del Cucapah No. 16822 Int.
A Col. EL LagoTijuana, B.C C.P.225210, Mexico

Product Name: BaXstrap

Basic UDI-DI: 0704543209937T7

Intended Purpose:

BaXstrap is 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 is intended to immobilize the head and neck in emergency situations, providing support and stability.

PadPack Alignment Pads are intended to be used to maintain the cervical spine in neutral alignment during immobilization.

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.

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

Laerdal Medical AS is certified by DNV Product Assurance AS to ISO 13485:2016.

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

Adrienne Farrington
Regulatory Affairs Specialist
on behalf of Alf Christian Dybdahl, CEO

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Adrienne Farrington

2025-07-30

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