

**Laerdal**
helping save lives

PRO-RP01-0140 Rev H

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: Laerdal Medical (Suzhou) Co., Ltd.
Building 18,19,20, No. 57 Huoju Road
Science & Technology Industrial Park
Suzhou, Jiangsu Province 215009
China

Product Name: **Stifneck Extrication Collar**

Basic UDI-DI: 0704543209933SX

Intended Purpose: Intended to support cervical spine in a neutral position during transportation, either alone or in combination with other cervical and full body immobilization devices (CSIDs and FBSIDs).

Product Options:

980100	Stifneck Baby, No-Neck Extrication Collar (US/AU)
98010033	Stifneck Baby, No-Neck Extrication Collar
980200	Stifneck Pediatric Extrication Collar (US/AU)
98002033	Stifneck Pediatric Extrication Collar
980300	Stifneck No-Neck Extrication Collar (US/AU)
98030033	Stifneck No-Neck Extrication Collar
980400	Stifneck Short Extrication Collar (US/AU)
98040033	Stifneck Short Extrication Collar
980500	Stifneck Regular Extrication Collar (US/AU)
98050033	Stifneck Regular Extrication Collar
980600	Stifneck Tall Extrication Collar (US/AU)
98060033	Stifneck Tall Extrication Collar

Accessories: 980700 Stifneck Carry Bag
to which this declaration relates is in conformity with the General Safety and Performance Requirements of EU Regulation 2017/745

Classification: The Stifneck Extrication Collars are class I according to rule 1 of Annex VIII of the EU Medical Device Regulation.

The Medical Device Accessory is 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 for Extrication Collars has been published 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



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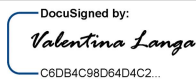
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