



**Laerdal**  
helping save lives

PRO-RP01-0141 Rev P

# 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 Huojia Road  
Science & Technology Industrial Park  
Suzhou, Jiangsu Province 215009  
China

**Product Name:** **Stifneck Select Extrication Collar**  
**Stifneck Pedi-Select Extrication Collar**

**Basic UDI-DI:** 0704543209932SV

**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:**

980010	Stifneck Select Extrication Collar (US/AU)
98001005	Stifneck Select Extrication Collar(J)
98001033	Stifneck Select Extrication Collar
980012	Stifneck Select Green Extrication Collar (US/AU)
98001205	Stifneck Select Green Extrication Collar (J)
98001233	Stifneck Select Green Extrication Collar
989910	Stifneck Select, Private Label (US/AU)
98991033	Stifneck Select, Private Label
980020	Stifneck Pedi-Select Extrication Collar (US/AU)
98002005	Stifneck Pedi-Select Extrication Collar(J)
98002033	Stifneck Pedi-Select Extrication Collar
989920	Stifneck Pedi-Select, Private Label (US/AU)
98992033	Stifneck Pedi-Select, Private Label

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

**Classification:** The Stifneck Select Extrication Collars 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 for Extrication Collars published at this time*

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

17.03.2021

Stavanger, Norway

DocuSigned by:

*Mari Kaada*

Mari Kaada

**Q&R Director**

on behalf of Alf Christian Dybdahl, CEO




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<p>Mari Kaada</p> <p>Mari.Kaada@laerdal.com</p> <p>Corporate Director Q&amp;R</p> <p>Laerdal Medical AS</p> <p>Security Level: Email, Account Authentication (None)</p>	
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