



Laerdal

helping save lives

PRO-RP01-0141 Rev O

EU DECLARATION OF CONFORMITY

Responsible Manufacturer: Laerdal Medical AS
P.O. Box 377
Tanke Svilandsgate 30
4002 Stavanger
Norway

Single Registration Number (SRN): *Not assigned at this date*

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 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
98001005	Stifneck Select Extrication Collar(J)
98001040	Stifneck Select Extrication Collar
98001049	Stifneck Select Extr. Collar, Americas
980012	Stifneck Select Green Extrication Collar*
98001205	Stifneck Select Green Extrication Collar(J)*
98001240	Stifneck Select Green Extrication Collar*
98001249	Stifneck Select Green Extr. Collar Americas
980020	Stifneck Pedi-Select Extrication Collar
98002005	Stifneck Pedi-Select Extrication Collar(J)
98002040	Stifneck Pedi-Select Extrication Collar
98002049	Stifneck Pedi-Select Extr. Collar, Americas
98991040	Stifneck Select, Private Label
98991049	Stifneck Select, Private Label, Americas
98992040	Stifneck Pedi-Select, Private Label
98992049	Stifneck Pedi-Select, Private Label, Americas

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.

Stavanger, 14 April 2020

Mari Kaada
Q&R Director
on behalf of Tore Lærdal, CEO

