

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 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.

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.

16.01.2023

Claudia Pajares Ibanez

Claudia Pajares Ibáñez Regulatory Affairs Manager on behalf of Alf Christian Dybdahl, CEO

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