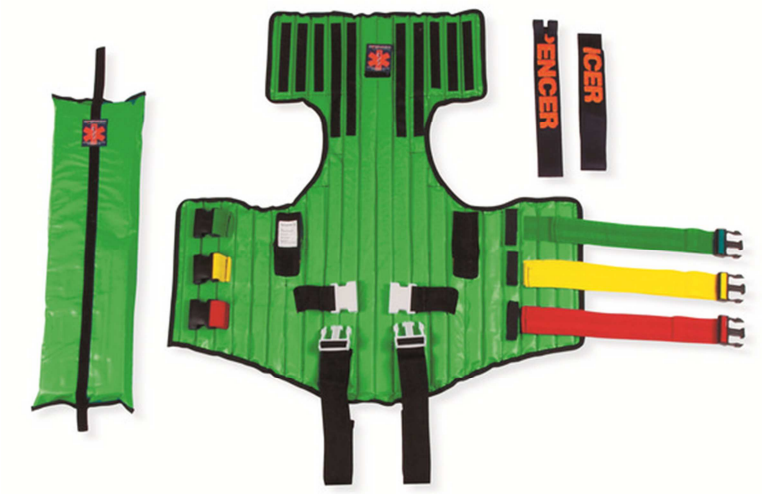
SED

Extrication/spine immobilization device



The SED extrication device is a first aid apparatus to be used for the extraction of a traumatised patient from a vehicle. It must be used after the application of the cervical collar to maintain immobilisation and head-torso alignment.

Specific features
Color coded belt system to make the application more intuitive and rapid
PVC coating for an easy sanitation
The separation of the rigid elements, allows high vertical rigidity and horizontal flexibility
Equipped with cushion for the nuchal area

Technical data	
Length	830 mm
Width	900 mm
Maximum thickness [1]	25 mm
Overall dimensions wrapped with bag (approx.)	850 x 250 x 120 mm
Belts length	74 ± 2 cm
Materials	PVC, Nylon, PP
Weight without bag	2,60 kg
Weight with bag	2,85 kg
Maximum load capacity	230 kg

[1] at the hooks

Standard equipment
Transport bag

Class I MD compliant with UE Reg. 2017/745	
SED SPENCER EXTRICATION DEVICE	CE
SR00111B	
CND Classification	V0804
Registration number	102330

NATO stock n° 6515-15-149-8710

Rev.0 (30/11/2020)

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EU DECLARATION OF CONFORMITY/ *DICHIARAZIONE DI CONFORMITA' UE*

Regulation/Regolamento UE 2017/745

The declaration is released under the sole responsibility of the manufacturer
La dichiarazione è rilasciata sotto la responsabilità esclusiva del fabbricante

Manufacturer/*Fabbricante:*	**Spencer Italia s.r.l.** Via Provinciale, 12 – 43038 Sala Baganza (PR) – Italy
Unique registration number/ *Numero di registrazione unico:*	Eudamed is not active/ *Banca Eudamed non attiva*
Medical Device/*Dispositivo Medico:*	SED SPENCER EXTRICATION DEVICE/ *SED - SPENCER EXTRICATION DEVICE C/SACCA*
Code /*Codice:*	SR00111B
BASIC UDI-DI /*UDI-DI di base:*	805771123ESTRICATORICZ
Lot/ *Lotto* SN/ *Matricola*	Not available before the production/ *Non disponibile prima della produzione*
Quantity/*Quantità:*	1
Risk class /*Classe di rischio:* (Annex VIII/*Allegato VII)*	I
Conformity assessment procedure/ *Procedura valutazione conformità*	Not present /*Non presente*
Rule/*Regola:*	1

Spencer Italia S.r.l. declares under its sole responsibility that the above mentioned medical device is in compliance with the requirements of the Regulation 2017/745 and with the applicable regulations and common specifications.
Spencer Italia S.r.l. *dichiara sotto la sua sola responsabilità che il Dispositivo Medico sopra menzionato, è conforme ai requisiti del Regolamento 2017/745, alle norme e alle specifiche comuni applicabili.*

The list of applicable standards is reported in the Technical File.
La lista delle norme applicabili è riportata nel relativo Fascicolo Tecnico.

Sala Baganza (PR) - IT, 14/05/2022

First name and surname /*Nome e cognome:*_____

Role/*Ruolo:* _____ Signature/*Firma:*_____

Person in whose name and on whose behalf this declaration of conformity has been signed/
Persona a nome e per conto della quale è stata firmata la presente Dichiarazione UE :

Antonio Ciardella
(Legal Representative /*Legale Rappresentante)*