



AB GERMA®

EU Declaration of conformity no. 200921-013

Product Name:	Vacuum Splint Set EasyFix PLUS + Vacuum Splint Full Leg EasyFix PLUS FNO
Intended use:	<p>The Vacuum Splint Set are primarily intended to be used in prehospital and hospital environment, by professional trained emergency and hospital personnel to safely stabilise injured patient extremities during transport. The Vacuum Splints are suited for fixation of patients with arm, hand, leg, ankle and foot injuries.</p> <p>Including: Vacuum splint Full Leg EasyFix PLUS Vacuum splint Lower Leg EasyFix PLUS Vacuum splint Arm EasyFix PLUS Vacuum Hand pump Repair Kit Bag for Splints Directions for use</p>
SRN: Basic UDI-DI: UDI DI: Germa Article No:	SE-MF-000003932 735001959P02VACSPLIGQ 07350019592625 24272115000
Manufacturer: Visiting address: Phone: Email: Web:	AB Germa Industrigatan 54-56, SE-29136 Kristianstad +46 (0)44 123030 info@germa.se www.germa.se
Product class:	Class I according to rule 1 in Annex VIII in MDR 2017/745
Conformity procedure:	Self-certification according to Annex IV in MDR 2017/745
Identification:	All products with serial numbers issued from; LOT number: 517470 Date: 2021-05-25 (yyyy-mm-dd).

Declaration statement;

This EU declaration of conformity is issued under the sole responsibility of the manufacturer AB Germa. The devices covered by this declaration is in conformity with the requirements in the European Medical Device Regulation 2017/745.

Signed in Kristianstad, Sweden on behalf of AB Germa by:

Position: Managing Director
Name: Björn Holmqvist
Date: 2021-05-23

Sign: 

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