



AB GERMA®

EU Declaration of conformity no. 200909-009

Product Name:	Vacuum Splint Full Leg EasyFix PLUS FNO
Intended use:	The vacuum splint 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 splint are suited for fixation of patients with leg, ankle and foot injuries. Including: Directions for use
SRN: Basic UDI-DI: UDI DI: Germa Article No:	SE-MF-000003932 735001959P02VACSPLIGQ 07350019592595 24272111000
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: 2021-05-25 Sign: _____

Postaddress/Postal address	Address/Goods address	Telefon/Phone	Telefax/Fax	E-mail/Web page	VAT No.	Bankgiro Bank account
AB GERMA Box 2127 SE-291 02 KRISTIANSTAD SWEDEN	Industrigatan 54-56 SE-291 36 Kristianstad	+46 (0)44-123030	+46 (0)44-10 31 79	info@germa.se www.germa.se	SE556086941301	481-4125