

EU Declaration of conformity no. 200909-027

Product Name:	Arm Vacuum splint 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 arm and wrist injuries. Including: Directions for use
SRN:	SE-MF-000003932
Basic UDI-DI:	735001959P02VACSPLIGQ
UDI DI:	07350019592618
Germa Article No:	24272113000
Manufacturer:	AB Germa
Visiting address:	Industrigatan 54-56, SE-29136 Kristianstad
Phone:	+46 (0)44 123030
Email:	info@germa.se
Web:	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

Postadress/Postal address

SWEDEN