

EU Declaration of conformity no. 200817-006

Product Name:	Vacuum mattress EasyFix PLUS FNO Ready2Go Kit
Intended use:	The vacuum mattress intended use is for prehospital and hospital environment, used by professional medical trained emergency and hospital personnel to stabilize the patient. Transport patients safely when in medical need of immobilization due to fractures and/ or suspected spinal injuries. The vacuum mattress have the capacities to be used and support safe patient handling, cocooning of patients and as a general patient transfer device.
	Including: Foot rest vacuum pump Repair kit Bag Instruction for use
SRN:	SE-MF-000003932
Basic UDI-DI:	735001959P01VACMATTDW
UDI DI:	07350019590959
Germa Article No:	24271511001
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: 2021-05-25

Sign

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VAT No.

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