



# AB GERMA®

## EU Declaration of conformity no. 200909-010

<b>Product Name:</b>	Vacuum Splint Lower Leg EasyFix PLUS FNO
<b>Intended use:</b>	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
<b>SRN:</b> <b>Basic UDI-DI:</b> <b>UDI DI:</b> <b>Germa Article No:</b>	SE-MF-000003932 735001959P02VACSPLIGQ 07350019592601 24272112000
<b>Manufacturer:</b> <b>Visiting address:</b> <b>Phone:</b> <b>Email:</b> <b>Web:</b>	AB Germa Industrigatan 54-56, SE-29136 Kristianstad +46 (0)44 123030 <a href="mailto:info@germa.se">info@germa.se</a> <a href="http://www.germa.se">www.germa.se</a>
<b>Product class:</b>	Class I according to rule 1 in Annex VIII in MDR 2017/745
<b>Conformity procedure:</b>	Self-certification according to Annex IV in MDR 2017/745
<b>Identification:</b>	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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