# EU Declaration of conformity no. 240830-001

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| **Product Name:** | Vacuum Splint Set Blue Line FLAF |
| **Intended use:** | The Vacuum Splint Set is 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.<br><br>Including: Vacuum splint Full Leg Blue Line<br>Vacuum Splint Arm Blue Line<br>Vacuum Splint Forearm Blue Line<br>Vacuum Hand pump<br>Repair Kit<br>Bag for<br>Directions for use |
| **SRN:**<br>**Basic UDI-DI:**<br>**UDI DI:**<br>**Germa Article No:** | SE-MF-000003932<br>735001959P02VACSPLIGQ<br>07350019597200<br>21272708000 |
| **Manufacturer:**<br>**Visiting address:**<br>**Phone:**<br>**Email:**<br>**Web:** | AB Germa<br>Industrigatan 54-56, SE-29136 Kristianstad<br>+46 (0)44 123030<br>info@germa.se<br>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;<br>LOT number: 531078<br>Date: 2024-08-16 (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: Patrik Tornström
Date: 2024-08-30

Sign: _____

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