

The SEGUF X®-System EU-Declaration of Conformity

In compliance with Article 52 No. 7 of the EU-Regulation EU 2017/745 of the Council for Medical Products (of April 5th, 2017)

> SEGUFIX°-Bandagen, Das Humane System GmbH & Co. KG (SRN: DE-MF-000027702),

hereby declares bindingly and under own responsibility that the fundamental requirements according to Annexes I of the reguliation are met for the following medical product:

Item 5745 SEGUFIX®-Stretcher Positioning Foot Velcro®

in the sizes offered according to the 2024 price list. Basic-UDI-DI = PP01531574542 / risk class = I

Intended use:

- positioning of one or both feet on stretchers
- also compatible for ambulance stretchers
- not a restraint (note: some jurisdictions consider Velcro® products as a restraint, should the patient not be able to remove them without help)

The conformity assessment procedure according to Annexes II and III of the EU regulation EU 2017/745 is applied. This declaration is valid from the issuing date until May 24th, 2026.

Jesteburg, May 25th, 2024

Date of issue - Executive Management -

R. W. de Sánchez

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Das SEGUF X®-System EU-Declaration of Conformity

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hereby declares bindingly and under own responsibility that the fundamental requirements according to Annexes I of the reguliation are met for the following medical product:

Item 2724, Item 2824 SEGUFIX®-Hand Restraint extended Velcro®

according to the 2024 price list. Basic-UDI-DI = PP01531272436 / risk class = I

Intended use:

- positioning of one or both hands in bed
- also compatible with ambulance stretchers
- not a restraint (note: some jurisdictions consider Velcro products as a restraint, should the patient not be able to remove them without help)

For use without SEGUFIX®-Standard with Crotch Strap or SEGUFIX®-Standard with Thigh Straps

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