

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 5243, Item 5343, Item 5443, Item 5143 SEGUFIX®-Stretcher Restraint Shoulder

in the sizes offered according to the 2024 price list. Basic-UDI-DI = PP01531524335 / risk class = I

Intended use:

- to secure patients on stretchers
- also compatible with ambulance stretchers
- physically restraining patients

Requirements:

SEGUFIX®-Hand Restraint extended and SEGUFIX®-Stretcher Restraint Foot required

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

R. W. de Sánchez - Executive Management -

SEGUFIX®-Bandagen · Das Humane System GmbH & Co. KG

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Das SEGUFEX®-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 5245, Item 5345, Item 5445, Item 5145 SEGUFIX®-Stretcher Restraint Foot

in the sizes offered according to the 2024 price list. Basic-UDI-DI = PP01531524537 / risk class = L

Intended use:

- restraint of one or both feet on stretchers
- also compatible with ambulance stretchers
- physically restraining patients

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

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