

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 7750 SEGUFIX®-Chair Belt Velcro® with Crotch Strap

in the sizes and versions offered according to the 2024 price list. Basic-UDI-DI = PP01531775040 / risk class = I

Intended use:

- to support and position patients in wheelchairs and other compatible chairs
- prevents the patient from sliding off of the seat
- pot 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

R. W. de Sánchez - Executive Management -

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

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Das SEGUF[§]X®-System

EU-Declaration of Conformity

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> 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 7280, Item 7380, Item 7480, Item 7180 SEGUFIX®-Transport Foot Restraint

in the sizes offered according to the 2024 price list. Basic-UDI-DI = PP01531728038 / risk class = I

Intended use:

- to position the feet of patients in wheelchairs and other compatible chairs
- attaches to the wheelchair with a lock
- 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.

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