

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 7770 SEGUFIX®-Transport Hand Strap Velcro®

according to the 2024 price list. Basic-UDI-DI = PP01531777042 / risk class = I

Intended use:

- to position the hands of patients on armrests of wheelchairs and other compatible chairs
- 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

R. W. de Sánchez - Executive Management -

SEGUFX -Bandagen · Das Humane System GmbH & Co. KG

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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 7780 SEGUFIX®-Transport Foot Restraint Velcro®

according to the 2024 price list. Basic-UDI-DI = PP01531778043 / risk class = I

Intended use:

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

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