

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 3240, 3241, 3242, 3243, 3244

Item 3340, 3341, 3342, 3343, 3344

Item 3440, 3441, 3442, 3443, 3444

Item 3140, 3141, 3142, 3143, 3144

SEGUFIX®-Extension Belt

in the versions offered according to the 2024 price list. Basic-UDI-DI = PP01531324029 / risk class = I

Intended use:

- extension belts for attachment on wider beds or backrests
- do not use to alter the size of products (e.g. waist belt)

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 3110/r SEGUFIX®-Brace Strap for legs

according to the 2024 price list. Basic-UDI-DI = PP01531311070 / risk class = I

Intended use:

- further restricts movement of legs
- physically restraining patients

Compatible with:

SEGUFIX®-Foot Restraint, SEGUFIX®-Thigh Restraint, SEGUEIX®-Quick Restraint Foot

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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