

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 6266, Item 6366, Item 6466, Item 6166 SEGUFIX®-Pelvic Belt

according to the 2024 price list. Basic-UDI-DI = PP01531626641 / risk class = I

Intended use:

- support belt for compatible chairs
- 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

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

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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 6276, Item 6376, Item 6476, Item 6176 SEGUFIX®-Pelvic Belt with Crotch Strap

according to the 2024 price list. Basic-UDI-DI = PP01531627642 / risk class = I

Intended use:

- support belt with eyelets for compatible chairs
- prevents patients from sliding off of the chair
- physically restraining patients

Requirement:

gap between backrest and seat

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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