

## 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 7240, Item 7340, Item 7440, Item 7140 Item 7246, Item 7346, Item 7446, Item 7146 SEGUFIX®-Chair Belt

in the sizes and versions offered according to the 2024 price list. Basic-UDI-DI = PP01531724034 / risk class = I

## Intended use:

- to support and position patients in wheelchairs and other compatible chairs
- physically restraining patients
- Item 7240, Item 7340, Item 7440: attaches behind the backrest with a snap lock
- Item 7246, Item 7346, Item 7446: attaches behind the backrest with a lock

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 SEGUFX®-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 7740 SEGUFIX®-Chair Belt Velcro®

in the sizes offered according to the 2024 price list. Basic-UDI-DI = PP01531774039 / risk class = I

## Intended use:

- to support and position patients in 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)
- attaches behind the backrest with a snap lock
- for a secure hold, the Velcro® fastener must overlap at least 250 mm / 9.8 inches

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