

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 regulation are met for the following medical product:

**Item 6216, Item 6316, Item 6416, Item 6116
SEGUFIX®-Transport Waist Belt**

in the sizes offered according to the 2024 price list.
Basic-UDI-DI = PP01531621636 / risk class = I

Intended use:

- to support patients in wheelchairs with a solid backrest,
automobiles and other compatible seats
- physically restraining patients

Requirements:

- SEGUFIX®-Backrest Strap (item 6730) required
- SEGUFIX®-Suspender Belt (item 6720) if needed

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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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 regulation are met for the following medical product:

**Item 6710
SEGUFIX®-Transport Waist Belt Velcro®**

in the sizes offered according to the 2024 price list.
Basic-UDI-DI = PP01531671035 / risk class = I

Intended use:

- to support patients in wheelchairs with a solid backrest,
automobiles and other compatible seats
- not a restraint (note: some jurisdictions consider Velcro®
products as a restraint, should the patient not be able
to remove them without help)

Requirements:

- SEGUFIX®-Backrest Strap (item 6730) required
- SEGUFIX®-Suspender Belt (item 6720) if needed
- for a secure hold, the Velcro® fastener must overlap
at least 250 mm / 9.8 inches

The conformity assessment procedure according to
Annexes II and III of the EU regulation EU 2017/745
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