

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 6720
SEGUFIX®-Suspender Belt

in the sizes offered according to the 2024 price list.
Basic-UDI-DI = PP01531672036 / risk class = I

Intended use:

- to support patients in wheelchairs with a solid backrest, automobiles and other compatible seats
- holds the patient in an upright position, prevents patient from sliding down
- not a restraint (note: some jurisdictions consider products with snap locks as a restraint, should the patient not be able to remove them without help)

Requirements:

SEGUFIX®-Backrest Strap and
SEGUFIX®-Transport Waist Belt required

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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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 6730
SEGUFIX®-Backrest Strap

in the sizes offered according to the 2024 price list.
Basic-UDI-DI = PP01531673037 / risk class = I

Intended use:

- to attach the SEGUFIX®-Transport Waist Belt and the SEGUFIX®-Suspender Belt to the backrest

Requirements:

- may not be used on folding wheelchairs with a soft backrest
- a gap between backrest and seat
- attaches to the backrest with Velcro® fastener
- for a secure hold, the Velcro® fastener must overlap at least 250 mm / 9.8 inches

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