

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 5204/r, Item 5304/r, Item 5404/r
Item 5104/r, Item 5101/r

SEGUFIX®-Hand Waist Restraint

in the sizes offered according to the 2024 price list.
Basic-UDI-DI = PP01531520431 / risk class = I

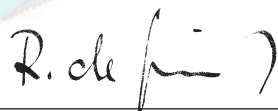
Intended use:

- to restrain hands of patients during transfer
(requires continuous monitoring)
- prevents patients from injuring themselves or others,
e. g. accompanying personnel during transfer
- 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

Allerbeeksring 33 • D-21266 Jesteburg • GERMANY • Phone: +49 (0) 4183 500-0
Fax: +49 (0) 4183 500-200 • E-Mail: export@segufix.de • Internet: www.segufix.com

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that the fundamental requirements according to Annexes I of
the regulation are met for the following medical product:

Item 5218, Item 5318, Item 5418, Item 5118
Item 5718 (with buckle lock)

SEGUFIX®-Restraining Aid

according to the 2024 price list.
Basic-UDI-DI = PP01531521870 / risk class = I

Intended use:

- provides assistance while restraining patients on stretchers
- after the restraint is applied, the SEGUFIX®-Restraining Aid may be removed
- additional stabilization of the patient
- can also be fastened above the knees
- also compatible for ambulance services
- **Item 5218, Item 5318, Item 5418 – with locking system:**
physically restraining patients
- **Item 5718 – with buckle lock:** not a restraint (note: some
jurisdictions consider products with buckle locks as a restraint,
should the patient not be able to remove them without help)

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