

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 2231, Item 2331, Item 2431, Item 2131
SEGUFIX®-Standard with Thigh Straps

in the sizes and versions offered according to the 2024 price list.
Basic-UDI-DI = PP01531223128 / risk class = I


Intended use:

- Patient restraint and positioning system in bed
- 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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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 2731
SEGUFIX®-Standard with Thigh Straps Velcro®

in the sizes and versions offered according to the 2024 price list.
Basic-UDI-DI = PP01531273134 / risk class = I

Intended use:

- positioning aid in bed, provides support for patients who feel insecure
- not a restraint (note: some jurisdictions consider Velcro® products as a restraint, should the patient not be able to remove them without help)

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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