

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 2250/r, Item 2350/r, Item 2450/r, Item 2150/r
SEGUFIX®-Compact

in the sizes and versions offered according to the 2024 price list.
Basic-UDI-DI = PP01531225070 / risk class = I

Intended use:

- patient restraint in bed
- prevents the patient from escaping upward or
downward while arms and legs remain unrestricted
- 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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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 8016
SEGUFIX®-Pull-up Line

according to the 2024 price list.
Basic-UDI-DI = PP01531801636 / risk class = I

Intended use:

- helps the patient to sit up in bed in an ergonomic manner,
preventing damage to the spine

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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