

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 4213/r, Item 4313/r, Item 4413/r, Item 4113/r
SEGUFIX®-Quick Restraint Shoulder

in the sizes and versions offered according to the 2024 price list.
Basic-UDI-DI = PP01531421330 / risk class = I

Intended use:

- patient restraint in bed, short term
- the SEGUFIX®-Quick Restraint Shoulder may only
be used in connection with additional restraint
measures for both hands and feet
- 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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of the Council for Medical Products (of April 5th, 2017)

SEGUFIX®-Bandagen,
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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 4214/r, Item 4314/r, Item 4414/r, Item 4114/r
SEGUFIX®-Quick Restraint Hand

in the sizes and versions offered according to the 2024 price list.
Basic-UDI-DI = PP01531421431 / risk class = I

Intended use:

- patient restraint of one or both hands in bed, short term
- 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.

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