The SEGUFIX®-System

EU-Declaration of Conformity

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 reguliation are met for the following medical product:

Item 4215/r, Item 4315/r, Item 4415/r, Item 4115/r
SEGUFIX®-Quick Restraint Foot

in the sizes and versions offered according to the 2024 price list.
Basic-UDI-DI = PP01531421532 / risk class = I

Intended use:
- patient restraint of one or both feet 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.

Jesteburg, May 25th, 2024
Date of issue

R. W. de Sánchez
– Executive Management –

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Das SEGUFIX®-System

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SEGUFIX®-Bandagen,
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(SRN: DE-MF-000027702),
hereby declares bindingly and under own responsibility
that the fundamental requirements according to Annexes I of
the reguliation are met for the following medical product:

Item 2217, Item 2317, Item 2417, Item 2117
SEGUFIX®-Head Positioning Belt

in the versions offered according to the 2024 price list.
Basic-UDI-DI = PP01531221770 / risk class = I

Intended use:
- to position the head in bed (requires continous monitoring)
- 5-point restraint required
- 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
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