

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 2203, Item 2303, Item 2403, Item 2103**  
**SEGUFIX®-Shoulder Restraint**

in the sizes and versions offered according to the 2024 price list.  
Basic-UDI-DI = PP01531220327 / risk class = I

**Intended use:**

- prevents the patient from sliding up out of the SEGUFIX®-Standard
- physically restraining patients


**Requirement:**

SEGUFIX®-Standard with Crotch Strap or  
SEGUFIX®-Standard with Thigh Straps

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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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 2212, Item 2312, Item 2412, Item 2112**  
**SEGUFIX®-Shoulder Additional Belt**

in the versions offered according to the 2024 price list.  
Basic-UDI-DI = PP01531221227 / risk class = I

**Intended use:**

- prevents the patient from sitting up in bed (requires continuous monitoring)
- physically restraining patients

**Requirements:**

SEGUFIX®-Standard with Crotch Strap / Thigh Straps  
and SEGUFIX®-Shoulder Restraint

**Compatible with:**

SEGUFIX®-Shoulder Restraint (not compatible with size XS)  
SEGUFIX®-Quick Restraint Shoulder, SEGUFIX®-Compact

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