

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 2204, Item 2304, Item 2404, Item 2104**  
**SEGUFIX®-Hand Restraint**

in the sizes and versions offered according to the 2024 price list.  
Basic-UDI-DI = PP01531220428 / risk class = I

**Intended use:**

- adjustable restraint of one or both hands in bed
- 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

Allerbeeksring 33 • D-21266 Jesteburg • GERMANY • Phone: +49 (0) 4183 500-0  
Fax: +49 (0) 4183 500-200 • E-Mail: export@segufix.de • Internet: www.segufix.com

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 2224, Item 2324, Item 2424, Item 2124**  
**SEGUFIX®-Hand Restraint extended**

in the sizes and versions offered according to the 2024 price list.  
Basic-UDI-DI = PP01531222430 / risk class = I

**Intended use:**

- adjustable restraint of one or both hands in bed
- physically restraining patients

For use **without** 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

Allerbeeksring 33 • D-21266 Jesteburg • GERMANY • Phone: +49 (0) 4183 500-0  
Fax: +49 (0) 4183 500-200 • E-Mail: export@segufix.de • Internet: www.segufix.com