

The SEGUF X®-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 6760 SEGUFIX®-Pelvic Belt (with Snap Lock)

according to the 2024 price list. Basic-UDI-DI = PP01531676040 / risk class = I

Intended use:

- support belt for compatible chairs
- not a restraint (note: some jurisdictions consider products with snap locks as a restraint, should the patient not be able to remove them without help)
- capacity of the snap lock up to 70 kg

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



Das SEGUFX®-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 6750 SEGUFIX®-Multi Belt Velcro®

in the sizes offered according to the 2024 price list. Basic-UDI-DI = PP01531675039 / risk class = I

Intended use:

- support belt for patients in chairs, armchairs and other compatible seats
- also compatible for ambulance stretchers, or for support on shower chairs
- not a restraint (note: some jurisdictions consider Velcro® products as a restraint, should the patient not be able to remove them without help)
- for a secure hold, the Velcro® fastener must overlap at least 250 mm / 9.8 inches

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 -

SEGUFX -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