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|-------------------------------------|---------------------------|--------------------------------|
| <b>EU Declaration of Conformity</b> |                           | <b>Product Family: Urology</b> |
| APPROVED BY:<br>TYTEX A/S           | VALID FROM:<br>2026-01-28 | VERSION NO.:<br>1.1            |

## EU Declaration of Conformity

**Manufacturers Name:** TYTEX A/S

**Manufacturers Address:** MARSVEJ 6, 7430 IKAST, DENMARK

**SRN:** DK-MF-000003620

**Product Family:** Urology

**Intended purpose:** Fixation of a urine bag on a thigh or calf.

**Classification:** Class I, rule I, non-sterile


**Conformity assessment route:** TYTEX A/S uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:

Class I: EU conformity declaration according to  
 Annex V CE marking of conformity.  
 Annex IX Conformity assessment based on a quality management system and assessment of the technical documentation.

This declaration of conformity is issued under the sole responsibility of TYTEX A/S. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

This declaration is supported by the Quality System approval to ISO 9001 and ISO 13485. All supporting documentation is retained at the premises of the manufacturer.

Signature:

  
 Ina Nemes  
 Head of Medical and  
 Regulatory Affairs

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DK-Ikast 2026.01.28:

# TYTEX®

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MAKING HEALTHCARE MORE HUMAN

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**Attachment to declaration of conformity**

| TYTEX          |              | Hartman IVF    |                             | Size          |
|----------------|--------------|----------------|-----------------------------|---------------|
| Article Number | Name         | Article Number | Name                        |               |
| 091554-01.01   | LeggyFix S   | 6254002        | Leggyfix Gr. S P10 K30      | S             |
| 091554-02.01   | LeggyFix S/M | 6254102        | Leggyfix Gr. S plus P10 K30 | S/M or S Plus |
| 091554-03.01   | LeggyFix M   | 6254202        | Leggyfix Gr. M P10 K30      | M             |
| 091554-05.01   | LeggyFix L   | 6254302        | Leggyfix Gr. L P10 K30      | L             |
| 091554-07.01   | LeggyFix XL  | 6254402        | Leggyfix Gr. XL P10 K30     | XL            |