



EC DECLARATION OF CONFORMITY

Manufacturer: **Fixus BV**
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SRN: **NL-MF-000010820**

This Declaration is issued under the sole responsibility of FIXUS BV;
The following **Risk Class 1** (Non-Sterile) products are covered under this declaration, as defined by Annex VIII of the Medical Device Regulation MDR 2017/745:

BASIC UDI-DI: 871810443TRAUMAMN		
Registration number at Dutch Ministry of Health:	Product range	Intended purpose
NL-CA002-2015-35275	FIXUS22*	External Trauma Fixator for broken (small) bones
NL-CA002-2015-35276	FIXUS33*	External Trauma Fixator for broken (small) bones with V-configuration
NL-CA002-2015-35277	FIXUS66*	External Trauma Fixator for short-term fixation with V-configuration

BASIC UDI-DI: 871810443RECONF3		
Registration number at Dutch Ministry of Health:	Product range	Intended purpose
NL-CA002-2012-25908	FIXUS88*	External Fixator for Reconstruction Adult and Pediatric

BASIC UDI-DI: 871810443QFIX5		
Registration number at Dutch Ministry of Health:	Product range	Intended purpose
NL-CA002-2019-47254	FIXUS VARIIS*	External Trauma Fixator for short-term fixation

*Including product annex's

We hereby declare that above mentioned product meets all applicable requirements of the Medical Device Regulation MDR 2017/745 as well as all applicable local regulations;

Medical device Identifier		
GMDN	48011	Orthopedic External Fixation System
UMDNS	15767	

Fixus BV maintains and has a DEKRA (0344) certified quality system according to EN ISO 13485:2016. Certification number: 2110147

Applicable standards:
MDR 2017/745
EN-ISO 13485: 2016
EN-ISO 14971: 2007 (2012)
NEN-EN 1041:2008
NEN-EN-ISO 15223-1 2016 (Cor. 2017-4)
ISO 10993-1
ASTM F1541

Issued: 23 August 2022
Expiry date: 23 August 2025

Company stamp and signature:



F.T.P. Verhaegh
Managing Director FIXUS BV

*** PRODUCT ANNEX'S**

Product range:

FIX22

FIXUS22

FIX33

FIXUS33

FIX66

FIXUS66

- Standard
- Hybrid
- Elbow
- Low Pilon

FIX88

Fixus88R Reconstruction Fixator accessories (adult)

Fixus88P Reconstruction Fixator and accessories (pediatric/ adult upper extremity)

VARIIS

Temporary trauma fixation and accessories