



Issue Number: 18

Approved By: H.JOHNSON

Date: 25.05.2022

QD 66 D

DECLARATION of CONFORMITY for registration of devices with the relevant Competent Authority

We, **Jenx Limited (Manufacturer)**
Wardsend Rd
Sheffield, S6 1RQ
United Kingdom
Tel.+44(0)1142853376
Fax+44(0)1142853528

SRN number GB – MF - 000016540

And our appointed EU Authorised Representative,

Advena Limited
Tower Business Centre, 2nd Floor,
Tower Street,
Swatar, BKR 4013
Malta
+ 356 2546 6689

SRN number MT – AR - 000000234

Hereby declare that the products specified on the products list below, meet the General Safety and Performance Requirements of Annex I and are in conformance with the provisions of the MEDICAL DEVICE REGULATION (MDR) 2017/745/EU. This declaration of conformity is issued under the sole responsibility of the manufacturer, and meets the requirements of Annex IV of the aforementioned regulation.

The devices specified on the product list below are classified as Class I, "Aids for Daily Living". The classification is based on the requirements of Rule 1 of annex VIII, of the MDR 2017/745/EU.

Jenx Limited operate a quality system which meets the requirements of ISO 9001:2015 as indicated on certificate No QAIC/UK/1964 -A , granted by Q.A. International Certification Limited, United Kingdom.

The requirements of ISO 13485:2016 as indicated on certificate No QA/UK/1896-A, granted by Q.A. International Certification Limited, United Kingdom.

The requirements of ISO 45001:2018 as indicated on certificate No 396962022, granted by Q.M.S. International Certification Limited, United Kingdom.

And the requirements of ISO 14001:2015 as indicated on certificate No 239380, granted by the British Assessment Bureau Certification Limited, United Kingdom.

The CE mark is applied under the guidelines of annex V of the MDR 2017/745/EU.

The CE marking has been affixed on the device according to Article 20 of the MDR 2017/745/EU

Jenx Manual Standers: GMDN code 61700

Product code	Product Name	Basic UDI-DI	Intended Purpose
NR70	Kangaroo & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
NR-50	Monkey & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
MUS01-F-08 MUS01-B-0*	Multistander Size 1 & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
MUS01-FABD	Multistander Abduction & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
MUS02-FM-08/ MUS02-B-0*	Multistander Size 2 Manual & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
NR55	Penguin & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
PS03	Prone Stander Size 1 & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
PS04	Prone Stander Size 2 & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements

STZ01-C1-0*	Standz & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
STZ01-0*	Standz base frame size 1 & corresponding components		
STZ01-AS-0*	Standz base frame assembled & corresponding components		
STZ01-AS1-0*	Standz base frame assembled & corresponding components		
STZ02-0*	Standz base frame size 2 & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
STZ02-AS-0*	Standz base frame size 2 assembled & corresponding components		
STZ02-AS1-0*	Standz base frame size 2 assembled & corresponding components		
SUP-01F	Supine Stander Size 1 & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
SUP-01B-0*			
SUP-02FM	Supine Stander Size 2 & corresponding components	50562352MANUALSTANDERSF	Standing system for children with postural support requirements
SUP-02B-0*			

*Indicates colour option

Signatory: Howard Johnson

Role: Quality and Health & Safety Compliance Manager

Signed.....

Date.....25.5.22



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The CE marking has been affixed on the device according to Article 20 of the MDR 2017/745/EU

Jenx Electric Standers: GMDN code 61702

Product code	Product Name	Basic UDI-DI	Intended Purpose
MUS02-FP-08/ MUS02-B-0*	Multistander Size 2 Powered & corresponding components	50562352ELECTRICSTANDER23	Standing system for children with postural support requirements with electronic actuator.
SUP-02FP SUP-02B-0*	Supine Stander Size 2& corresponding components	50562352ELECTRICSTANDER23	Standing system for children with postural support requirements with electronic actuator.
SUP-03S-0*/ SUP-03F SUP-03B-0*	Supine Stander Size 3& corresponding components	50562352ELECTRICSTANDER23	Standing system for children with postural support requirements with electronic actuator.

*Indicates colour option

Signatory: Howard Johnson

Role: Quality and Health & Safety Compliance Manager

Signed.....

Date.....25.5.22