



Issue Number: 18

Approved By: H.JOHNSON

Date: 25.05.2022

QD 66 E

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

We, **Jenx Limited (Manufacturer)**
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SRN number GB – MF - 000016540

And our appointed EU Authorised Representative,

Advena Limited
Tower Business Centre, 2nd Floor,
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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 Assistive sleeping cushion set: GMDN code 63407

Product code	Product Name	Basic UDI-DI	Intended Purpose
DC06	Cot Dreama & corresponding components	50562352MATTRESSCOVSETPU	24-hour sleep positioning system for children with postural support requirements
DC51	Cot Bed Dreama & corresponding components	50562352MATTRESSCOVSETPU	24-hour sleep positioning system for children with postural support requirements
DC03	Standard Dreama & corresponding components	50562352MATTRESSCOVSETPU	24-hour sleep positioning system for children with postural support requirements
DC15	Extra Long Dreama & corresponding components	50562352MATTRESSCOVSETPU	24-hour sleep positioning system for children with postural support requirements

Signatory: Howard Johnson

Role: Quality and Health & Safety Compliance Manager

Signed.....

Date.....25.5.22