



QD 66 E

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

We, **Jenx Limited (Manufacturer)**
Wardsend Rd
Sheffield, S6 1RQ
United Kingdom
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And our appointed EU Authorised Representative,

Advena Limited
Tower Business Centre, 2nd Floor,
Tower Street,
Swatar, BKR 4013
Malta
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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 V111, 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. 417, granted by BM Trada 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.

And the requirements of ISO 14001:2015 as indicated on certificate No QA/UK/1940-A, granted by Q.A. International 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 Mattress/Cover Sets: GMDN code 62365

Product code	Product Name	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..... 15.2.2021