naturwell

EU DECLARATION OF CONFORMITY

Manufacturer:

Polcrux-Bis Marcin Opala ul. Jesiotrowa 13/1, 93-460 Łódź

CE

MEDICAL DEVICE:

Trade name: MATTRESS

Model:

- FOAM MATTRESS TENDER
- FOAM MATTRESS ORTOPEDIC
- PREMIUM
- ORGANIC
- NATURWELL BASIC
- NATURWELL PREMIUM

Classification of medical devices:
class I, rule 1.

Intended use:

- spinal pain prevention,
- support for postural defect physical therapy process
- prevention of developmental defects in the human locomotor system (musculoskeletal system)

We declare, under our own responsibility, that the foregoing medical devices comply with the requirements of the Regulation (EU) no. 2017/745 of the European Parliament and of the Council dated 5 April 2017 on medical devices and their harmonised standards:

KOD BASIC UDI-DI: 59037715MATERACV5

Nr referencyjny	Tytuł	Data wydania
PN-EN ISO 10993-1:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing in the risk management process	2010 2013
PN-EN 1041+A1:2013-12	Information supplied by the manufacturer of medical devices	2012
PN-EN ISO 14971:2012	Medical devices – Application of risk management to medical devices	2017
PN-EN ISO 15223-1:2017-02	Medical devices – Symbols to be used in the labels of medical devices, their markings and provided information – Part 1: General requirements.	

Signature of authorised person
Marcin Opala, Owner

POLCRUX-BIS
Marcin Opala
ul. Jesiotrowa 13, 93-460 Łódź
NIP 7292608159 REGON 101840489

Official seal

Date of declaration: 20.08.2021 r., **place:** Łódź