Czeladź, 26.02.2024

EU DECLARATION OF CONFORMITY

according regulation EU 2017/745 of 5th April 2017 for medical devices

Manufacturer:

Reha-Bed Sp. z o.o.

Actor ID/SRN: PL-MF-000040289

based in 41-253 Czeladź, ul Spacerowa 1, Polska

Declare medical devices

Nursing care bed

type:

TAURUS JUNIOR

Basic UDI-DI: 59041832TRJUNIORH3

CE

model(s):

TR/JUNIOR, TR/JUNIOR/LOW, 1275/JUNIOR, 1275/JUNIOR/STD, 1275/PETITE/LOAK/FSR, 1275/PETITE/STD/LOAK/FSR

It is hereby declared that the medical equipment listed above, marked CE is medical device of First Class, rule 13, in accordance with Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices[1]. Issuing of the declaration of conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of regulation EU 2017/745.

The bed is intended to support the patient's weight while sleeping or resting. It assists in the care and/or ensures comfort for the patient or caregiver – when the bed is used in long-term care facilities.

In Reha-Bed, there is implemented the Quality Management System conformable with the requirements of the standard ISO 9001:2015.

Medical equipment is in conformity with the following European standards:

- EN ISO 14971:2019
- EN 60601-1:2006+AC:2010
- EN 60601-2-52:2010 + A1:2015
- EN 60601-1-6:2010
- EN 62366:2015

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Antoni Brud
Prezes Zarządu

The sole responsibility for issuing this declaration of conformity lies with the manufacturer.

Antoni Brud
CEO of Reha-bed sp. z o.o.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)