

# EC DECLARATION OF CONFORMITY

This declaration is issued under the responsibility of the manufacturer: **PROMA REHA, s. r. o.**

**Company address:** Riegrova 342, 552 03 Česká Skalice

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Registration number according to Art. 31(EUDAMED)



## Classification of a medical device:

Class I, non-sterile – without measuring function

## Purpose of use: Electrically adjustable special lever bed

Determined for treatment support, mitigation and compensation of injury or disability of the patient under medical supervision.

**Name of the medical device:**

**GENEO**

**Options:**

-

**Basic UDI-DI:**

**8594202320537**

## DECLARATION

I declare that the above mentioned medical device complies with all requirements stated in the Government Regulation and Council(EU) 2017/745 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 and a statement that the device also complies with all other relevant European Union legislation.

Measures have been taken to ensure that all products placed on the market comply with the technical documentation.

## References to any common specifications used in relation to which conformity is declared:

- Act No. 89/2021 Coll. on medical devices and on the amendment of Act No. 378/2007 Coll., on pharmaceuticals and on amendments to certain already established Acts (Act on pharmaceuticals), as amended.
- Government Regulation No. 481/2012 Coll., Restrictions on the use of certain hazardous substances in electrical and electronic equipment.
- Act No. 22/1997 Coll. on technical requirements for products and on Amendments and additions to certain Acts  
Compliance with relevant articles of standards EN 60601-1 ed.2 + A11 + A1 + A12 + Opr.1:2016, EN 60601-1-2 ed.3:2016, EN 60601-2-52 + Opr.1 + A1:2015, EN 60601-1-6 ed.3:2010, EN ISO 14971:2012, EN 1041+A1:2014 and EN ISO 15223-1:2012 as amended.

## CERTIFICATION

**Integrated management system**

QMS – ČSN EN ISO 9001:2016  
QMS – ČSN EN ISO 13485 ed.2:2016  
EMS – ČSN EN ISO 14001:2016

v.21-2

In Česká Skalice

03. 05. 2021



**Radek Jakubský**  
CEO

Signed for and on behalf of **PROMA REHA, s.r.o.**

