The Technology of Human Performance

EU Declaration of Conformity

We hereby declare under our sole responsibility that the Simulator II system meets the relevant provisions of the following European Union Directives:

- Council **Directive 93/42/EEC** of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC (**MDD**)
- **Directive 2006/42/EC** of the European Parliament and of the Council of 17 May 2006 on machinery as amended by Regulation (EU) 2019/1243
- **Directive 2011/65/EU** of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (**RoHS**)

The Simulator II has undergone a conformity assessment procedure required by the MDD and is manufactured in harmony with the Technical Documentation compiled as defined in the relevant Directives and retained by BTE.

Product information in regard to the **MDD** and **RoHS** Directives:

Manufacturer 	BTE Technologies 7455-L New Ridge Road Hanover, MD 21076, USA www.btetechnologies.com Telephone: 410.850.0333 Email: Service@btetechnologies.com
Product Identification	**Device Trade Name**: Simulator II **Device Name**: Simulator II **Model**: Sim II 5
UDI-DI	SIM II 5: 10850390007151
EMDN (CND) code	Z120616 - PHYSICAL THERAPY AND REHABILITATION SYSTEMS
Intended Purpose	The Simulator is intended to be used for musculoskeletal testing and exercise. The application is physical rehabilitation. The system is intended to measure strength to identify deficits, increase muscle strength and endurance, and track patient progress through the process. It may be used for upper extremity and lower extremity muscle weakness.
Device Classification (MDD)	Class I
Classification Rule (MDD)	Rule 12

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Route to Compliance (MDD)	Annex VII of the Medical Devices Directive
Device Classification (MDR)	Class IIa
Classification Rule (MDR)	Rule 11
CE Marking Provision	Under **Medical Device Regulation (EU) 2017/745 (MDR)**, the device will be up-classified to class IIa due to changed software classification rules. Based on the MDR Article 120 §3, the SIMULATOR II can be placed on the EU market as a class I device until May 26, 2024 provided that the device • will continue to comply with the MDD, • there will be no significant changes in the design and intended purpose, and • the device will comply with the MDR requirements for post market surveillance, vigilance, and registration of economic operators and of devices
Authorized Representative EC REP	Emergo Europe Prinsessegracht 20 2514 AP, The Hague The Netherlands Telephone: +31.70.345.8570 Emails: EmergoEurope@ul.com EmergoVigilance@ul.com

The device is CE marked since 2001.

Signed for on behalf of BTE Technologies

E Kaczanowska

Ewa Kaczanowska
PRRC/Regulatory Manager
BTE Technologies

Hanover, MD May 20, 2021