


## 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:

<b>Manufacturer</b> 	BTE Technologies 7455-L New Ridge Road Hanover, MD 21076, USA <a href="http://www.btetechnologies.com">www.btetechnologies.com</a>	Telephone: 410.850.0333 Email: <a href="mailto:Service@btetechnologies.com">Service@btetechnologies.com</a>
<b>Product Identification</b>	<b>Device Trade Name:</b> Simulator II <b>Device Name:</b> Simulator II <b>Model:</b> Sim II 5	
<b>UDI-DI</b>	SIM II 5: 10850390007151	
<b>EMDN (CND) code</b>	Z120616 - PHYSICAL THERAPY AND REHABILITATION SYSTEMS	
<b>Intended Purpose</b>	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.	
<b>Device Classification (MDD)</b>	Class I	
<b>Classification Rule (MDD)</b>	Rule 12	

<b>Route to Compliance (MDD)</b>	Annex VII of the Medical Devices Directive
<b>Device Classification (MDR)</b>	Class IIa
<b>Classification Rule (MDR)</b>	Rule 11
<b>CE Marking Provision</b>	<p>Under <b>Medical Device Regulation (EU) 2017/745 (MDR)</b>, 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</p> <ul style="list-style-type: none"> <li>• will continue to comply with the MDD,</li> <li>• there will be no significant changes in the design and intended purpose, and</li> <li>• the device will comply with the MDR requirements for post market surveillance, vigilance, and registration of economic operators and of devices</li> </ul>
<b>Authorized Representative</b> 	<p>Emergo Europe  Prinsessegracht 20  2514 AP, The Hague  The Netherlands</p> <p>Telephone: +31.70.345.8570  Emails: <a href="mailto:EmergoEurope@ul.com">EmergoEurope@ul.com</a>  <a href="mailto:EmergoVigilance@ul.com">EmergoVigilance@ul.com</a></p>

The device is CE marked since 2001.

Signed for on behalf of BTE Technologies



Ewa Kaczanowska  
PRRC/Regulatory Manager  
BTE Technologies

Hanover, MD

May 20, 2021



The Technology of Human Performance

## Addendum to the original Declaration of Conformity

Per 31 January 2023, the address of our EU Authorized Representative as listed on the original DoC has changed.

OLD ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

NEW ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

COMPANY REPRESENTATIVE:

Ewa Kaczanowska  
Regulatory Manager/PRRC

June 2, 2023

### EU Declaration of Conformity - Amendment

We hereby declare under our sole responsibility that BTE and the BTE Simulator meet the relevant provisions of the following European Union Regulation:

- **Regulation (EU) 2023/607** of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (Text with EEA relevance)

Product information regarding Regulation (EU) 2023/607:

MDD Declaration of Conformity	BTE Declaration of Conformity for an MDR up-classified MDD Class I self-certified device remains valid.
NB Application	BTE has applied for EU MDR CE Marking with the Notified Body (Intertek Medical Notified Body AB, Notified Body Number NB 2862) prior to May 26, 2024 (January 23, 2024).
NB Signed Written Agreement	BTE has applied for EU MDR CE Marking with the Notified Body (Intertek Medical Notified Body AB, Notified Body Number NB 2862) prior to September 26, 2024. Once application is approved, signed written agreement will be performed.
CE Marking provision	Under Regulation (EU) 2023/607, the device may continue to be placed on the market after <b>May 26, 2024</b> , provided the specified conditions continue to be met, including: <ul style="list-style-type: none"> <li>• will continue to comply with the MDD (93/42/EEC)</li> <li>• no significant change in design or intended purpose</li> <li>• the device will comply with the MDR requirements for post market surveillance, vigilance, and registration of economic operators and devices</li> </ul>
Legacy CE mark criteria	Regulations (EU) 2017/745, (EU) 2023/607: "Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028." Article 120.3b

Signed for on behalf of BTE Technologies:

*Eric Finegan* Mar 20, 2024

Eric Finegan  
 PRRC/Quality and Regulatory Manager  
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 BTE Technologies  
 Hanover, MD

March 20, 2024