

## EU Declaration of Conformity


We hereby declare under our sole responsibility that the Eccentron 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 product also complies with the applicable requirements in the Swedish law 1993:584 and the Swedish Medical Products Agency regulation LVFS 2003:11 regarding medical devices.

The Eccentron 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 **Medical Device Directive 93/42/EEC**:

<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> Eccentron <b>Device Name:</b> Eccentron <b>Model:</b> LE1	
<b>UDI-DI</b>	10850390007816	
<b>EMDN (CND) code</b>	Z120616 - PHYSICAL THERAPY AND REHABILITATION SYSTEMS	
<b>Intended Purpose</b>	The system is intended to be used to increase muscle strength of the lower extremities.	
<b>Device Classification (MDD)</b>	Class IIa	
<b>Classification Rule (MDD)</b>	Rule 9	
<b>Route to Compliance (MDD)</b>	Annex II of the Medical Devices Directive	
<b>Device Classification (MDR)</b>	Class IIa	
<b>Classification Rule (MDR)</b>	Rule 11	



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<b>CE Marking Provision</b>	<p>CE Certificate issued by the notified body in accordance with MDD is valid until May 26, 2024. Based on the <b>Medical Device Regulation (EU) 2017/745 (MDR)</b> Article 120 §3, the Eccentron can be placed on the EU market 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<sup>1</sup></b> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-top: 5px;"> <span style="border-right: 1px solid black; padding: 0 5px;">EC</span> <span style="padding: 0 5px;">REP</span> </div>	<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>
<b>Notified Body</b>	<p>Intertek Semko AB  Torshamnsgatan 43  Box 1103  SE-164 22 Kista  Sweden</p>	<p>Notified Body ID Number 0413  Certificate Number 41319556</p>

The device is CE marked since 2014.

Signed for on behalf of BTE Technologies

Ewa Kaczanowska  
PRRC/Regulatory Manager  
BTE Technologies

Hanover, MD

May 20, 2021

<sup>1</sup> AR for MDD and RoHS Directives



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## 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 Eccentron 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 Certificate	BTE maintains an MDD Certificate that had not expired prior to March 20, 2023.
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 lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices lawfully placed on the market from 26 May 2021 pursuant to paragraphs 3, 3a, 3b and 3f of this Article, may continue to be made available on the market or put into service." Article 120.4

Signed for on behalf of BTE Technologies:

*Eric Finegan* Mar 20, 2024

Eric Finegan  
 PRRC/Quality and Regulatory Manager  
 Regulatory@btetechnologies.com  
 BTE Technologies  
 Hanover, MD

March 20, 2024