The Technology of Human Performance

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**:

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

PHONE 410.850.0333 TOLL FREE 800.331.8845
FAX 410.850.5244
ADDRESS 7455-L New Ridge Road | Hanover, MD 21076
WEB btetechnologies.com

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CE Marking Provision	CE Certificate issued by the notified body in accordance with MDD is valid until May 26, 2024. Based on the **Medical Device Regulation (EU) 2017/745 (MDR)** Article 120 §3, the Eccentron can be placed on the EU market 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[i] EC REP	Emergo Europe Prinsessegracht 20 2514 AP, The Hague The Netherlands	Telephone: +31.70.345.8570 Emails: EmergoEurope@ul.com EmergoVigilance@ul.com
Notified Body	Intertek Semko AB Torshamnsgatan 43 Box 1103 SE-164 22 Kista Sweden	Notified Body ID Number 0413 Certificate Number 41319556

The device is CE marked since 2014.

Signed for on behalf of BTE Technologies

E Kaczanowska

Ewa Kaczanowska
PRRC/Regulatory Manager
BTE Technologies

Hanover, MD May 20, 2021

[i] 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:

E Kaczanowska

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 **May 26, 2024**, provided the specified conditions continue to be met, including: • will continue to comply with the MDD (93/42/EEC) • no significant change in design or intended purpose • the device will comply with the MDR requirements for post market surveillance, vigilance, and registration of economic operators and devices
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

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