# EU Declaration of Conformity

We hereby declare under our sole responsibility that the Primus 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 Primus 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<br>7455-L New Ridge Road<br>Hanover, MD 21076, USA<br>www.btetechnologies.com<br>Telephone: 410.850.0333<br>Email:<br>Service@btetechnologies.com. |
| **Product Identification** | **Device Trade Name**: PrimusRS<br>**Device Name**: Primus **Model**: PrimusRS (PRRS) |
| **UDI-DI** | 10850390007243 |
| **EMDN (CND) code** | Z120616 - PHYSICAL THERAPY AND REHABILITATION SYSTEMS |
| **Intended Purpose** | The Primus is intended to be used for musculoskeletal strength testing and exercise. Applications include physical rehabilitation and sports therapy. The system is intended to measure strength, increase muscle strength and endurance, and track patient progress through the process. It may be used for upper extremity, lower extremity, and trunk 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 PRIMUS can be placed on the EU market as a class I device until May 26, 2024 provided that the device<br>• will continue to comply with the MDD,<br>• there will be no significant changes in the design and intended purpose, and<br>• the device will comply with the MDR requirements for post market surveillance, vigilance, and registration of economic operators and of devices |
| **Authorized Representative**<br>EC REP | Emergo Europe<br>Prinsessegracht 20<br>2514 AP, The Hague<br>The Netherlands<br>Telephone: +31.70.345.8570<br>Emails: EmergoEurope@ul.com<br>EmergoVigilance@ul.com |

The device is CE marked since 2004.

Signed for on behalf of BTE Technologies

E Kaczanowska

Ewa Kaczanowska
PRRC/Regulatory Manager
BTE Technologies

Hanover, MD May 20, 2021

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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<br>2514 AP The Hague<br>The Netherlands | +31.70.345.8570 - phone<br>EmergoEurope@ul.com |

| NEW ADDRESS AUTHORIZED REPRESENTATIVE | | |
|---|---|---|
| **Name of company** | **Address** | **Telephone/email** |
| Emergo Europe | Westervoortsedijk 60<br>6827 AT Arnhem<br>The Netherlands | +31.70.345.8570 - phone<br>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 Primus 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:

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|---|---|
| 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 **May 26, 2024**, provided the specified conditions continue to be met, including:<br>• will continue to comply with the MDD (93/42/EEC)<br>• no significant change in design or intended purpose<br>• 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 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
Regulatory@btetechnologies.com
BTE Technologies
Hanover, MD March 20, 2024

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