DECLARATION OF CONFORMITY

CE 2797

NormaTec Industries, LP
CE Certificate Number CE621634
480 Pleasant Street, Suite A200
Watertown, Massachusetts
United States of America, 02472

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Trade Name (Model Number): Normatec 3 (REJ6)

The object of the declaration described above is in conformity with:

- Council Directive 93/42/EEC concerning medical devices.
- 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 manufacturer has been certified by the Notified Body noted below to ISO 13485 and complies with Annex II excluding section 4 of the Medical Device Directive.

- Classification: Class IIa in accordance with Annex IX, rule 9 of the Medical Device Directive 93/42/EEC

Notified Body: BSI Group The Netherlands BV
Say Building John M Keynesplein 9
1066 EP Amsterdam
The Netherlands
+31 20 346 0780

Note that the Notified Body number does not apply to the RoHS Directive.

Authorized Representative: Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands
+31 70 345 8570

The Quality Management Representative is Steve Henderson.

Normatec 3, as indicated above, is a system that includes charger, control device, hose, and attachments (Legs, Arms or Hip). Compatibility of the entire system was tested to the standards in the table below. They are packaged as a system to the user with relevant user instructions from the manufacturer. All activity is governed by internal control and inspection by the manufacturer. Products described above and labeled with the “CE Mark” are in conformance with the current revisions of:

Standard No.	Title
AIM 7351731	Medical electrical equipment and system electromagnetic immunity test for exposure to radio frequency identification readers
ANSI C63.27-2017	Evaluation of Wireless Coexistence
EN 301 489-1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-17	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems.
EN 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Collateral standard: Electromagnetic Compatibility - Requirements and Tests
EN 60601-1-11	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 60601-1-6	Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices
EN 62366-1	Medical devices - Application of usability engineering to medical devices

Steve Henderson
Director of Quality Systems & Regulatory Systems

27 December 2022
Date