EU Declaration of Conformity (MDR)

Levitate Technology ApS
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External Prosthetic Components

UDI-DI (574500024000, 574500024001, 574500024002, 574500024003, 574500024004, 574500024005, 574500024006)

Trade name (Levitate Blade, Levitate Blade Kit, Levitate Quick Change, Levitate Forever Foot)

Levitate Prosthetic Components are ankle and foot devices and adaptors manufactured to create a spring-like components that when mounted to other appropriate components such as knees or sockets will act like an energy storing device used for walking, running, jogging, and recreational activities.

The devices are Class I devices.

Statements:

This declaration of conformity is issued under the sole responsibility of Levitate Technology ApS

The device is covered by the present EU declaration is in conformity with the (EU) MDR 2017/745, and tested along with ISO 10328:2016 Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods.

Date: 06.06.2023

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