Pretorian
TECHNOLOGIES LTD.

DECLARATION OF CONFORMITY

PRODUCT CATEGORY: Mains Appliance Controllers

INTENDED PURPOSE: Mains appliance switching device to allow a user with a disability such as a motor impairment to easily turn on/off everyday appliances such as lamps. Various input methods are accommodated such as wired switches, wireless switches and tablet/phone apps. Not a life support device, nor a method for switching a critical appliance.

PRODUCT FAMILY: Energise UK (non-sterile device)
Energise EU (non-sterile device)
iClick UK (non-sterile device)
iClick EU (non-sterile device)

PRODUCT	SKU	GMDN	Basic UDI	UDI-DI
Energise UK	ENZUK	35465	506089563MNS1EF	5060895630251
Energise EU	ENZEU	35465	506089563MNS1EF	5060895630268
iClick UK	ICLKUK	35465	506089563MNS1EF	5060895630275
iClick EU	ICLKEU	35465	506089563MNS1EF	5060895630282

CLASSIFICATION:

Classified as **Class I** self-declaration devices by applying **Rule No. 01** of Annex VIII of the Medical Devices Regulation (MDR 2017/745).

CONFORMITY ASSESSMENT ROUTE:

MDR 2017/745, Annex V – Self Declaration, Annex III - Generation and Maintenance of this Technical File to demonstrate compliance with the relevant General Safety & Performance Requirements (GSPR) of MDR 2017/745 - Annex I.

Pretorian Technologies Ltd. hereby declares under its sole responsibility as manufacturer that the product has correct packaging and the relevant information and instructions required for use of the products. All manufacturing activities are subjected to the appropriate methods of internal quality control and inspection. We declare that the above-mentioned products meet the provisions of Medical Device Regulation MDR 2017/745 relating to medical devices and is classified in that field as a **Class I non-invasive, non-sterile self-declaration medical device.** All supporting documentation is retained at the premises of the Manufacturer. Pretorian Technologies' Quality System and Technical Documentation is not subject to Notified Body surveillance; however, our devices **are** registered as Class I self-declaration products with the HPRA in the Republic of Ireland.

HPRA REGISTRATION NUMBER: **MDROEO202103102549**

EUDAMED SRN: **GB-MF-000008344**

NOTIFIED BODY: Not applicable

MANUFACTURER:
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Date: 22-Feb-2023