Pretorian
TECHNOLOGIES LTD.

DECLARATION OF CONFORMITY

PRODUCT CATEGORY: iPad Access Device family

INTENDED PURPOSE: Electronic interfaces to allow users with a disability to use a computing device with a touch screen, such as a mobile telephone or tablet computer, where their disability might otherwise prevent them from using such a device. Input method is either by way of button switches which may or may not form part of the product, or a joystick. Not a life support device, nor a method of controlling a life support device.

PRODUCT FAMILY: APPlicator (non-sterile device)
Switch2Scan (non-sterile device)
SimplyWorks for iPad (non-sterile device)
J-Pad (non-sterile device)
iControl (non-sterile device)

PRODUCT	SKU	GMDN	Basic UDI	UDI-DI
APPlicator	APPL	30969	506089563BTIFDA	5060895630640
Switch2Scan	SW2SC	30969	506089563BTIFDA	5060895630657
SimplyWorks for iPad	SW4IPD	30969	506089563BTIFDA	5060895630664
J-Pad	JPAD	30969	506089563BTIFDA	5060895630671
iControl	ICTRL	30969	506089563BTIFDA	5060895630688

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

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