Pretorian
TECHNOLOGIES LTD.

DECLARATION OF CONFORMITY

PRODUCT CATEGORY: Switch Interface family

PRODUCT FAMILY:

Simple Switch Interface (non-sterile device)
SimplyWorks Send (non-sterile device)
SimplyWorks Send-6 (non-sterile device)
SimplyWorks Control Lite (non-sterile device)
SimplyWorks Control (non-sterile device)
SimplyWorks Control Pro (non-sterile device)
Freedom (non-sterile device)
Track-It (non-sterile device)
Test-It (non-sterile device)

PRODUCT	SKU	GMDN	Basic UDI	UDI-DI
Simple Switch Interface	SSI	30969	506089563INT1DN	5060895630527
SimplyWorks Send	SWSND	30969	506089563INT1DN	5060895630534
SimplyWorks Send-6	SWSND6	30969	506089563INT1DN	5060895630541
SimplyWorks Control Lite	SWCTLL	30969	506089563INT1DN	5060895630558
SimplyWorks Control	SWCTL	30969	506089563INT1DN	5060895630565
SimplyWorks Control Pro	SWCTLP	30969	506089563INT1DN	5060895630572
Freedom	FRDM	30969	506089563INT1DN	5060895630589
Track-It	TRKIT	30969	506089563INT1DN	5060895630596
Test-It	TSTIT	30969	506089563INT1DN	5060895630602

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 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**

NOTIFIED BODY: Not applicable

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Date: 10-Mar-2021