

DECLARATION OF CONFORMITY

PRODUCT CATEGORY: Switch family

PRODUCT FAMILY: Smoothie 125 (non-sterile device)
Smoothie 75 (non-sterile device)
SimplyWorks Switch 125 (non-sterile device)
SimplyWorks Switch 75 (non-sterile device)
EnvirON Switch 125 (non-sterile device)
EnvirON Switch 75 (non-sterile device)
Simple Switch Interface Switch Set (non-sterile device)
SimplyWorks Switch Set (non-sterile device)
iSwitch (non-sterile device)
USB Switch (non-sterile device)

PRODUCT	SKU	GMDN	Basic UDI	UDI-DI
Smoothie 125mm Switch Red	SMOO5R	30969	506089563SWS1H6	5060895630299
Smoothie 125mm Switch Yellow	SMOO5Y	30969	506089563SWS1H6	5060895630305
Smoothie 125mm Switch Green	SMOO5G	30969	506089563SWS1H6	5060895630312
Smoothie 125mm Switch Blue	SMOO5B	30969	506089563SWS1H6	5060895630329
Smoothie 75 mm Switch Red	SMOO3R	30969	506089563SWS1H6	5060895630336
Smoothie 75 mm Switch Yellow	SMOO3Y	30969	506089563SWS1H6	5060895630343
Smoothie 75 mm Switch Green	SMOO3G	30969	506089563SWS1H6	5060895630350
Smoothie 75 mm Switch Blue	SMOO3B	30969	506089563SWS1H6	5060895630367
SimplyWorks Switch 125 Wireless Switch Red	SWS5R	30969	506089563SWS1H6	5060895630374
SimplyWorks Switch 125 Wireless Switch Yellow	SWS5Y	30969	506089563SWS1H6	5060895630381
SimplyWorks Switch 125 Wireless Switch Green	SWS5G	30969	506089563SWS1H6	5060895630398
SimplyWorks Switch 125 Wireless Switch Blue	SWS5B	30969	506089563SWS1H6	5060895630404
SimplyWorks Switch 75 Wireless Switch Red	SWS3R	30969	506089563SWS1H6	5060895630411
SimplyWorks Switch 75 Wireless Switch Yellow	SWS3Y	30969	506089563SWS1H6	5060895630428
SimplyWorks Switch 75 Wireless Switch Green	SWS3G	30969	506089563SWS1H6	5060895630435
SimplyWorks Switch 75 Wireless Switch Blue	SWS3B	30969	506089563SWS1H6	5060895630442
EnvirON Switch 125 Wireless Switch Red	ENVS5R	30969	506089563SWS1H6	5060895630459
EnvirON Switch 125 Wireless Switch Yellow	ENVS5Y	30969	506089563SWS1H6	5060895630466
EnvirON Switch 125 Wireless Switch Green	ENVS5G	30969	506089563SWS1H6	5060895630473
EnvirON Switch 125 Wireless Switch Blue	ENVS5B	30969	506089563SWS1H6	5060895630480
EnvirON Switch 75 Wireless Switch Red	ENVS3R	30969	506089563SWS1H6	5060895630497
EnvirON Switch 75 Wireless Switch Yellow	ENVS3Y	30969	506089563SWS1H6	5060895632507
EnvirON Switch 75 Wireless Switch Green	ENVS3G	30969	506089563SWS1H6	5060895632514
EnvirON Switch 75 Wireless Switch Blue	ENVS3B	30969	506089563SWS1H6	5060895632521
Simple Switch Interface Switch Set	SSISSET	30969	506089563SWS1H6	5060895632538
SimplyWorks 75mm Switch Set	SSSRY	30969	506089563SWS1H6	5060895632545
iSwitch Bluetooth Switch Red	ISWR	30969	506089563SWS1H6	5060895632552
iSwitch Bluetooth Switch Yellow	ISWY	30969	506089563SWS1H6	5060895632569
iSwitch Bluetooth Switch Green	ISWG	30969	506089563SWS1H6	5060895632576
iSwitch Bluetooth Switch Blue	ISWB	30969	506089563SWS1H6	5060895632583
USB Switch Purple	USBSWP	30969	506089563SWS1H6	5060895632590

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

EUDAMED SRN:

GB-MF-000008344

NOTIFIED BODY:

Not applicable

MANUFACTURER:

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Date: 05-Mar-2021