

DECLARATION OF CONFORMITY

PRODUCT CATEGORY:	Switch family
INTENDED PURPOSE:	Button switches to be used as input method by a user with a disability, such as a motor impairment. They may variously be used as a selection method, a means for scanning through a list or series of icons and many other potential applications, depending on the hardware and software it is connected to. Not a life support device, nor a method of controlling a life support device.
PRODUCT FAMILY:	Smoothie 125 (non-sterile device) Smoothie 125 (Large Jack) (non-sterile device) Smoothie 125 (Normally Closed) (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) Grasp Switch (non-sterile device) Leaf Switch (non-sterile device) ToFFEE Wired Switch (non-sterile device) ToFFEE Bluetooth Switch (non-sterile device) Savvy Switch (non-sterile device) iSwitch50 (non-sterile device)

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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EU REPRESENTATIVE:

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Signature:



David Gilbert
Managing Director, Pretorian Technologies Ltd.

Date: 9-January-2026

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PRODUCT	SKU	GMDN	Basic UDI	UDI-DI
Smoothie 125mm Switch Red	SMO05R	30969	506089563SWS1H6	5060895630299
Smoothie 125mm Switch Yellow	SMO05Y	30969	506089563SWS1H6	5060895630305
Smoothie 125mm Switch Green	SMO05G	30969	506089563SWS1H6	5060895630312
Smoothie 125mm Switch Blue	SMO05B	30969	506089563SWS1H6	5060895630329
Smoothie 125mm Switch Red (Large Jack)	SMO05LJR	30969	506089563SWS1H6	5060895630817
Smoothie 125mm Switch Yellow (Large Jack)	SMO05LJY	30969	506089563SWS1H6	5060895630824
Smoothie 125mm Switch Green (Large Jack)	SMO05LJG	30969	506089563SWS1H6	5060895630831
Smoothie 125mm Switch Blue (Large Jack)	SMO05LJB	30969	506089563SWS1H6	5060895630848
Smoothie 125mm Switch Red (Normally Closed)	SMO05NCR	30969	506089563SWS1H6	5060895630855
Smoothie 125mm Switch Yellow (Normally Closed)	SMO05NCY	30969	506089563SWS1H6	5060895630862
Smoothie 125mm Switch Green (Normally Closed)	SMO05NCG	30969	506089563SWS1H6	5060895630879
Smoothie 125mm Switch Blue (Normally Closed)	SMO05NCB	30969	506089563SWS1H6	5060895630886
Smoothie 75 mm Switch Red	SMO03R	30969	506089563SWS1H6	5060895630336
Smoothie 75 mm Switch Yellow	SMO03Y	30969	506089563SWS1H6	5060895630343
Smoothie 75 mm Switch Green	SMO03G	30969	506089563SWS1H6	5060895630350
Smoothie 75 mm Switch Blue	SMO03B	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	ENV55R	30969	506089563SWS1H6	5060895630459
EnvirON Switch 125 Wireless Switch Yellow	ENV55Y	30969	506089563SWS1H6	5060895630466
EnvirON Switch 125 Wireless Switch Green	ENV55G	30969	506089563SWS1H6	5060895630473
EnvirON Switch 125 Wireless Switch Blue	ENV55B	30969	506089563SWS1H6	5060895630480
EnvirON Switch 75 Wireless Switch Red	ENV53R	30969	506089563SWS1H6	5060895630497
EnvirON Switch 75 Wireless Switch Yellow	ENV53Y	30969	506089563SWS1H6	5060895632507
EnvirON Switch 75 Wireless Switch Green	ENV53G	30969	506089563SWS1H6	5060895632514
EnvirON Switch 75 Wireless Switch Blue	ENV53B	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
Grasp Switch	GRASPSW	30969	506089563SWS1H6	5060895630930
Leaf Switch	LEAFSW	30969	506089563SWS1H6	5060895630947
ToFFEE Wired Switch	TOFSW	30969	506089563SWS1H6	5060895630978
ToFFEE Bluetooth Switch	TOFBT	30969	506089563SWS1H6	5060895630992
Savvy Switch	SAVSW	30969	506089563SWS1H6	5060895630985
iSwitch50	ISW50	30969	506089563SWS1H6	5060895630961

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