

DECLARATION OF CONFORMITY

PRODUCT CATEGORY: Wireless Receiver family

PRODUCT FAMILY: SimplyWorks Receive (non-sterile device)
SimplyWorks Receive:2 (non-sterile device)
SimplyWorks Receive Micro (non-sterile device)

PRODUCT	SKU	GMDN	Basic UDI	UDI-DI
SimplyWorks Receive	SWRX	30969	506089563SWRXKF	5060895630619
SimplyWorks Receive:2	SWRX2	30969	506089563SWRXKF	5060895630626
SimplyWorks Receive Micro	SWTXM	30969	506089563SWRXKF	5060895630633

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

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