Pretorian
TECHNOLOGIES LTD.

DECLARATION OF CONFORMITY

PRODUCT CATEGORY: Joysticks

PRODUCT FAMILY:
n-ABLER Joystick (non-sterile device)
Optima Joystick (non-sterile device)
Optimax Joystick (non-sterile device)
SimplyWorks Joystick (non-sterile device)
Jazz Joystick (non-sterile device)
Ultra Joystick (non-sterile device)
Blueline Joystick (non-sterile device)
Slimline Joystick (non-sterile device)

PRODUCT	SKU	GMDN	Basic UDI	UDI-DI
n-ABLER Joystick	NABJ	36899	506089563JSK1DT	5060895630169
n-ABLER Pro Joystick	NABJP	36899	506089563JSK1DT	5060895630176
Optima Joystick	OPMAJ	36899	506089563JSK1DT	5060895630183
Optimax Joystick	OPMXJ	36899	506089563JSK1DT	5060895630190
SimplyWorks Joystick	SWJ	36899	506089563JSK1DT	5060895630206
Jazz Joystick	JAZZJ	36899	506089563JSK1DT	5060895630213
Ultra Joystick	ULTRA	36899	506089563JSK1DT	5060895630220
Blueline Joystick	BLULN	36899	506089563JSK1DT	5060895630237
Slimline Joystick	SLMJS	36899	506089563JSK1DT	5060895630244

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

MANUFACTURER:
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Signature:

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Managing Director, Pretorian Technologies Ltd. Date: 05-Mar-2021