Pretorian
TECHNOLOGIES LTD.

DECLARATION OF CONFORMITY

PRODUCT CATEGORY: Trackballs and Trackpads

PRODUCT FAMILY: n-ABLER Trackball (non-sterile device)
Optima Trackball (non-sterile device)
Optimax Trackball (non-sterile device)
SimplyWorks Trackball (non-sterile device)
Orbitrack (non-sterile device)

PRODUCT	SKU	GMDN	Basic UDI	UDI-DI
n-ABLER Trackball Red	NABTR	36899	506089563TKB1DW	5060895630107
n-ABLER Trackball Blue	NABTB	36899	506089563TKB1DW	5060895630114
n-ABLER Pro Trackball	NABTP	36899	506089563TKB1DW	5060895630121
Optima Trackball	OPMAT	36899	506089563TKB1DW	5060895630138
Optimax Trackball	OPMXT	36899	506089563TKB1DW	5060895630145
SimplyWorks Trackball	SWT	36899	506089563TKB1DW	5060895630152
Orbitrack Trackpad	ORB	36899	506089563TKB1DW	5060895630510

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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Date: 05-Mar-2021