Pretorian
TECHNOLOGIES LTD.

DECLARATION OF CONFORMITY

PRODUCT CATEGORY: AAC Devices

INTENDED PURPOSE: Electronic record/ playback devices to augment communications for individuals with speech/ language impairments by allowing recorded messages to be played back in differing sequences. May also be used by younger users who do not possess such impairments. Not a life support device, nor a sole communication aid.

PRODUCT FAMILY: Smooth Talker (non-sterile device)
Smooth Talker with Levels (non-sterile device)
AACtivity (non-sterile device)

PRODUCT	SKU	GMDN	Basic UDI	UDI-DI
Smooth Talker Red	STR	30910	506089563AAC18A	5060895630008
Smooth Talker Yellow	STY	30910	506089563AAC18A	5060895630015
Smooth Talker Green	STG	30910	506089563AAC18A	5060895630022
Smooth Talker Blue	STB	30910	506089563AAC18A	5060895630039
Smooth Talker All Colours	STRHV	30910	506089563AAC18A	5060895630046
Smooth Talker with Levels Red	STWLR	30910	506089563AAC18A	5060895630053
Smooth Talker with Levels Yellow	STWLY	30910	506089563AAC18A	5060895630060
Smooth Talker with Levels Green	STWLG	30910	506089563AAC18A	5060895630077
Smooth Talker with Levels Blue	STWLB	30910	506089563AAC18A	5060895630084
Smooth Talker with Levels All Colours	STWLRHV	30910	506089563AAC18A	5060895630091
AACtivity	AACTVTY	30910	506089563AAC18A	5060895630503

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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Signature:

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Date: 22-Feb-2023