Declaration of Conformity

Company	Smartbox Assistive Technology Ltd.
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Authorised Representative	REHAVISTA GmbH Konsul-Smidt-Str. 8c 28217 Bremen Germany
Phone	0421 - 989 628 - 0

We, Smartbox Assistive Technology Ltd. under our sole responsibility, declare that the product listed below:

Type of Product	Communication Aid
Description	A dedicated communication aid supplied with Grid 3 software and service package. The device can be used with and has been tested with switch, pointer, and eye gaze access methods. It can be supplied with or without these accessories.
Product Name	Grid Pad 13
Model Number	GP13A
UDI (Unique Device Identifier)	5060446901373

The object of this declaration is a Class I Medical Device and is in conformity with the following EU harmonised legislation:

2017/745	The EU Regulation on Medical Devices (MDR)
2011/65/EU	ROHS
2012/19/EU	WEEE
1907/2006	REACH

The following harmonized and/or unharmonized standards and technical specifications have been applied:

ISO 14971:2019	Application of risk management to medical devices
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC / EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 61000-3-3:2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current < = 16 A per phase and not subject to conditional connection
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

This declaration is sign on behalf of Smartbox Assistive Technology Ltd by:

Simon Poole
2024 02 12
Group Chief Technology Officer