



Declaration of Conformity

Company Smartbox Assistive Technology Ltd.
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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 15 |
| Model Number | GP15A |
| UDI (Unique Device Identifier) | 5060446901205 |

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 |

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

| | |
|--------------------------------|---|
| ISO 14971:2012 | 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:

Dougal Hawes
2021 04 30
Managing Director