



Declaration of Conformity

Smartbox Assistive Technology Ltd.

Address Smartbox Assistive Technology Ltd.
Ysobel House
Malvern
Worcestershire
WR14 1JJ
United Kingdom
Phone +44 (0) 1684 578868
Web www.thinksmartbox.com

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

Type of Product Communication Aid
Product Name Touch Pad
Model Numbers ST10A, ST10B
UDI (Unique Device Identifier) 5060446901182

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:

EN 60950-1:2006+A2:2013 Information technology equipment. General safety requirements
ISO 14971:2012 Application of risk management to medical devices
EN 55032:2012/AC:21013 Electromagnetic compatibility (EMC) of multimedia equipment. Emission Requirements
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:

Barney Hawes
2020 08 06
Managing Director