Declaration of Conformity

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

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	Eye tracking camera
Description	An eye tracking camera used to control a Grid Pad
Product Name	Alea
Model Number	ALEA-KIT12/15
UDI (Unique Device Identifier)	5060446901199

The object of this declaration is an accessory to 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 14971:2019	Application of risk management to medical devices
IEC / EN 60950-1:2005	Audio/video, information and communication technology equipment. Safety requirements
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 62471:2006	Photobiological safety of lamps and lamp systems.
EN 60825-1:2014	Safety of laser products

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

Simon Poole
2022 10 24
Technical Director