



Declaration of Conformity

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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 communication aid comprising Microsoft tablet computer, Grid 3 software and service package. It is supplied with documentation and accessories to support use.

Product Name Touch Pad

Model Numbers ST10B, ST10B-8GB

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:

BS EN ISO 14971:2019 Application of risk management to medical devices
IEC / EN 60601-1-2:2015 Medical electrical equipment – Electromagnetic disturbances

This product comprises a Microsoft Surface Go 2 and Bluetooth speaker. These components apply standards not named by 2017/745 on appendices below. Although these are not named, they reflect the level of risk when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness.

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

Dougal Hawes
2021 04 30
Managing Director

Appendix A

Tablet Computer Manufacturer: Microsoft Corp.
Manufacturer Address: One Microsoft Way, Redmond, WA, 98052-6399
Model: Surface Go 2 (1926)

Legislation

Legislation

2014/53/EU
2009/125/EC
2011/65/EU

RF & EMC

Standards

EN 300 328, V2.2.2
EN 300 330, V2.1.1
EN 300 440, V2.1.1
EN 301 489-1, V2.2.3
EN 301 489-3, V2.1.1
EN 301 489-17, V3.2.4
EN 301 489-19, V2.1.1
EN 301 489-52
EN 301 893, V2.1.1
EN 301 908-1, V11.1.1
EN 301 908-2, V11.1.2
EN 301 908-13, V11.1.2
EN 303 413, V1.1.1

Safety Article 3.1a

Standards

EN 50566: 2017
EN 55024:2010
EN 55032:2012/AC:2013
EN 55035:2017
EN 62368-1:2014/A11:2017

Environmental

Standards

EC No 1275/2008
EC No 801/2013
IEC 63000:2018

Appendix B

Speaker Manufacturer: Lenovo (Singapore) Pte. Ltd.
Manufacturer Address: 151 Lorong Chuan, #02-01 New Tech Park, Singapore, 556741
Model: Lenovo Bluetooth Speaker LX001

Legislation

Legislation

2014/35/EU LVD
2014/53/EC RED
2011/65/EU ROHS

RF & EMC

Standards

EN 55032:2015
EN 61000-3-2:2014
EN 61000-3-3:2013
EN 300 328 V2.1.1
EN 300 330 V2.1.1
EN 301 489-1 V2.2.0
EN 301 489-3 V2.1.1
EN 301 489-17 V3.2.0

Safety

Article 3.1a

Standards

EN 60950-1:2006+A1:2010+A11:2009+A12:2011+A2:2013

Environmental

Standards

ROHS EN 50581:2012
EC 278/2009