



Declaration of Conformity

Under the sole responsibility of Tobii Dynavox AB, Danderyd, Sweden, SRN SE-MF-000008884, we hereby declare that the product identified herein complies with the following directives and standards:

EU Directives

- EU 2017/745 Medical Device Regulation, Class I, Rule 13
- EU2015/863 Restrictions of Hazardous Substances Directive (RoHS 3)
- 2014/30/EU Electromagnetic Compatibility Directive (EMC)
- 2014/53/EU Radio Equipment Directive (RED)
- REACH and WEEE Directives

Product Information & Use

Type of product: **Speech Generating Device (SGD), aka Augmentative and Alternative Communication (AAC) Device**

Product name/Model: **Tobii Dynavox SC Tablet (for 10.2" iPad) Part # 113509 Device Identifier (base UDI)**

7340074601806

Product description: **Deployed/Configured iPad 10.2" with Accessory Case and Speech Communication Software**

Intended use: **The SC Tablet device is designed for people that have challenges in their ability to speak due to injury, disability or illness.**

Other Directives & Standards


- ISO 13585:2016
- Part 820 cGMP for USA & EU 93/42/EEC, Class I, Rule 12 for UK
- Federal Communications Commission (FCC), CFR Title 47, Part15 Subpart B: 2015, CLASS B Industry Canada Equipment Standard (ICES-003), Issue 6: 2016 Class B
- Radiocommunication Standard 2008 (ACMA), AS/NZS CISPR 32:2015
- IATA UN 38.3 & IEC 62133:2012 (Second Edition)

The following standards have been used:

- | | |
|---------------------------------------|----------------------------|
| • ISO 14971:2019 (Risk Mgmt. Med Dev) | • IEC 55032:2015 |
| • IEC 62368-1:2014 (includes LVD) | • IEC 61000-3-2:2019 |
| • EN 62368-1:2014 + A11:2017 | • EN 6100-3-3:2013+A1:2019 |
| • EN 301 489-1 draft 489-17 | • EN55035:2017 |
| • EN 300 328 | |
| • EN 62479:2010 | |

Note: For iPad 10.2, a component of the SC Tablet, see Apple's website for DoC.

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all essential requirements.

DocuSigned by:

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2022-08-29 | 16:24 PDT

Anthony J. Pavlik, Chief Operating Officer

Date

Signed in Pittsburgh, Pennsylvania USA

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