



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

- Medical Device Regulation (EU) 2017/745 Class I, Rule 13. (MDD, Class I, Rule 12)
- EU2015/863 Restrictions of Hazardous Substances Directive (RoHS)
- 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 Mini (incl. iPad Mini 6), Part # 113538, Device Identifier/GTIN (base UDI) 7340074601929**

Product description: **An iOS based product designed to meet the needs of individuals who cannot speak due to injury, disability or illness. The durable, portable unit comes with touch screen and communications software, to provide a better quality of life for people with difficulty communicating.**

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

Other Directives & Standards

- Federal Communications Commission (FCC), CFR Title 47, Part15 Subpart B: 2015, CLASS B Industry Canada Equipment Standard (ICES-003), Issue 7
- Radiocommunication Standard 2008 (ACMA), AS/NZS CISPR 32:2015
- IATA UN 383 & IEC 62133:2012 (Second Edition)
- IEC 60601-1-2:2014 & EN60601-1-2:2015 (Medical Device Safety) + IEC 62368 (ITE Safety)
- UKCA LVD  + all National differences.
- IEC 62366-1 Usability
- IEC 60529 Ingress Protection

The following standards have been used:

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| • ISO 14971:2019 (Risk Mgmt. Med Dev) | • IEC 55032:2015+A1:2020 |
| • EN IEC 62368-1:2020+A11:2020 | • IEC 61000-3-2:2019+A1:2021 |
| • EN 301 489-1 v.2.2.3, 489-17 v.3.2.4 | • EN 61000-3-3:2013+A1:2019+A2:2021 |
| • EN 300 328 v.2.2.2 | • EN55035:2017+A11:2020 |
| • EN 62479:2010 | |

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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Anthony J Pavlik, Chief Operating Officer
Signed in Pittsburgh, Pennsylvania USA

2022-08-30 | 10:19 PDT

Date

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