



Declaration of Conformity

Under the sole responsibility of Tobii Dynavox AB, SRN SE-MF-000008884, herby declares that the product identified herein complies with the following directives for the TD Pilot, along with its components and parts relevant to the total system configuration:

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)
- REACH and WEEE Directives

Product Information & Use

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

Product name/Model: **TD Pilot - UDI 7340074601769**

Product description: **Deployed/Configured iPad Pro with Accessory Pack capable of Eye tracking, along with Speech Communication Software.**

Intended use: **The TD Pilot 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 (Quality System Med. Dev.)
- 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 7
- CISPR 32:2015
- IATA UN 38.3 & IEC 62133:2012 (Second Edition)
- IEC 60601-1-11 Medical Electrical Equipment for Basic Safety and Essential Performance

Additional information on standards used:

- | | |
|---|-----------------------------|
| • ISO 14971:2019 (Risk Mgmt. Med Dev) | • IEC 55032:2015 + A11:2020 |
| • IEC 62368-1:2018+IEC 62368-1:2020+A11:2020 (includes LVD, ITE Safety) | • IEC 61000-3-2:2019 |
| | • EN 6100-3-3:2013+A1:2019 |
| | • EN55035:2017 + A11:2020 |

Note: For iPad a component of the TD Pilot, 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:


10/27/2021

Anthony J. Pavlik, VP of Global Operations
Signed in Pittsburgh, Pennsylvania USA

Date

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