tobii dynavox

Declaration of Conformity $C\epsilon$

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

- 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: Accessory Case for iPad

Product name/Model: Tobii Dynavox Speech Case (for 10.2" iPad), Part # 12008618, Device Identifier/GTIN (base UDI) 7340074601738

Product description: An accessory case for iPad by Apple which adds better speaker/sound quality for speech output, and switch accessibility.

Intended use: The Tobii Dynavox Speech Case is intended to use in conjunction with an iPad device by people using communication software applications on iOS (e.g. Compass or Snap + CoreFirst) for communication. The case adds better speaker quality and switch access functionality for the users.

Other Directives & Standards

- 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 383 & IEC 62133:2012 (Second Edition)

The following standards have been used:

- ISO 14971:2019 (Risk Mgmt. Med Dev)
- IEC 62368-1:2014 (includes LVD)
- EN 62368-1:2014 + A11:2017
- EN 301 489-1 draft 489-17
- EN 300 328
- EN 62479:2010

- IEC 55032:2015
- IEC 61000-3-2:2019
- EN 6100-3-3:2013+A1:2019
- EN55035:2017

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:

2022-08-29 | 16:24 PDT

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

Date

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