tobii dynavox

Declaration of Conformity CE

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

EU Directives

- Medical Device Regulation (EU) 2017/745 Class I, Rule 13.
- 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**

Trademark: **Tobii Dynavox**

Product name/Model: **Tobii Dynavox, TD Navio Midi, Part # 1000798, Device Identifier/GTIN (base UDI) 7340074602056.**

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, TD Navio Midi device is for people that have challenges in their ability to speak due to injury, disability or illness.**

Other Directives & Standards

- ISO 13485:2016 + ISO 9001:2015
- Federal Communications Commission (FCC), CFR Title 47, Part15 Subpart B: 2015, CLASS B Industry Canada Equipment Standard (ICES-003), Issue 7. FDA Class II, 510K Exempt
- IATA UN 38.3 & IEC 62133-2:2017/AMD1:2021 (Battery Safety)
- IEC 60601-1:2005/AMD1:2012+AMD2:2020, IEC 60601-1-11:2015+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+A1:2020, EN 60601-1-2:2015+A1:2021, IEC TR 60601-402:2016 (Medical Device Safety)
- IEC 62368-1:2018 (ITE Safety)
- IEC 62366-1:2015/AMD1:2020 Usability
- IEC 60529:1989/AMD2:2013/COR1:2019 Ingress Protection

The following standards have been used:

- ISO 14971:2019 (Risk Mgmt. Med Dev)
- EN IEC 62368-1:2020+A11:2020
- EN55035:2017+A11:2020
- EN 55032:2015+A1:2020 + A1:2020
- IEC 61000-3-2:2019+A1:2021
- EN 61000-3-3:2013+A1:2019+A2:2021

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:
Susanne Peroni
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2024-08-09 | 18:44 CEST

Susanne L Peroni, Regulatory and QMS Manager — Date

Signed in Pittsburgh, Pennsylvania USA

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