

Declaration of Conformity

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

- **Medical Device Regulation (EU) 2017/745** effective 26/05/2021, **Class I, Rule 13**
- **Low Voltage Directive (LVD) 2014/35/EU** (incl. in IEC 62368)
- **Radio Equipment Directive (RED) 2014/53/EU**
- **Electromagnetic Compatibility (EMC) 2014/30/EU**
- **REACH Directive 2006/121/EC, 1907/2006/EC Annex 17**
- **UN38.3 (Battery Transport)**
- **Electrical Safety Medical 93/42/EEC** (IEC 60601 inc. Amendment 1 and Amendment 2:2022)
- **RoHS 3 Directive (EU 2015/863)**
- **Battery Directive 2013/56/EU**
- **WEEE Directive 2012/19/EU**
- **Electrical Safety IT/AV (IEC 62368-1 CB)**

Type of product: Speech Generating Device

Product name/model: Tobii Dynavox TD I-110, Product # 1000727, Device UDI 7340074602094

Product Description: Tobii Dynavox TD I-110 is a Windows-based computer 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 I-110 is a Windows SGD, including communication software for people that have challenges in their ability to speak due to injury, disability or illness.

The following relevant standards are used for EU conformity:

- ISO14971:2019 (Medical Devices Risk Management)
- ISO 13485:2016 (Quality System Registered with Intertek)
- IEC 62366-1 (Usability)
- IEC 60529 Ed. 2.2: 2013 (Ingress Protection)

DocuSigned by:

Susanne Peroni

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Susanne Peroni
Quality System and Regulatory Manager
Tobii Dynavox LLC & Tobii Dynavox AB

2024-09-16 | 16:23 CEST

Date
Signed in Pittsburgh, Pennsylvania