

Declaration of Conformity

Under the sole responsibility of Dynavox Group AB, Stockholm, Sweden 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)
- **RoHS 3 Directive** (EU 2015/863)
- **Battery Directive** 2013/56/EU
- **WEEE Directive** 2012/19/EU
- **Electrical Safety IT/AV** (IEC 62368-1)

Type of product: Speech Generating Device

Product name/model: Tobii Dynavox TD I-16, Product # 1000255, Device UDI 7340074601110
Tobii Dynavox TD I-16, Product # 1001172, Device UDI 7340074602131

Product Description: Tobii Dynavox TD I-16 is a Windows-based device designed to meet the needs of individuals who cannot speak due to injury, disability or illness. The unit comes with a 13,3-inch touch screen, communications software and optional eye control, to provide a better quality of life for people with reduced physical ability.

Intended use: The Tobii Dynavox I-16 is a Windows SGD, 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)
- IEC 62366-1 (Usability)
- IEC 60529 Ed. 2.2: 2013 (Ingress Protection)
- IEC 62471 (Photobiological Safety – Eye tracker)
- IEC 62133/UL 2054 Battery Safety

Signed by:

Susanne Peroni

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Susanne Peroni
Regulatory Manager
Dynavox Group AB

2025-04-17 | 19:11 CEST

Date
Signed in Pittsburgh, Pennsylvania