



### Declaration of Conformity

Under the sole responsibility of Tobii Dynamox, 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 Dynamox TD I-16, Product # 1000255, Device UDI 7340074602001

Product Description: Tobii Dynamox 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 Dynamox 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

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Anthony Pavlik  
Chief Operating Officer  
Tobii Dynamox LLC & Tobii Dynamox AB

2023-05-17 | 21:30 CEST

Date  
Signed in Pittsburgh, Pennsylvania