



EU Declaration of Conformity

Legal manufacturer	
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Product Details	
Product	TD Pilot 2
Basic UDI-DI	7340074602223V6
EAN	07340074602179

Eu Declaration of Conformity Information	
SRN	SE-MF-000008884
Intended Purpose	Speech Generating Device
EU Risk Classification (MDR Annex VIII)	A Class I device according to rule 11

Other EU Directives and Standards

- Medical Device Regulation (EU) 2017/745 effective 26/05/2021, Class I, Rule 11
- Electrical Safety Medical MDR (IEC 60601)
- Low Voltage Directive (LVD) 2014/35/EU (incl. in IEC 62368)
- Radio Equipment Directive (RED) 2014/53/EU
- RoHS 3 Directive (EU 2015/863)
- Electromagnetic Compatibility (EMC) 2014/30/EU
- Eu Battery Regulations (EU) 2023/1542
- Reach Directive 2006/121/EC, 1907/2006/EC Annex 17
- WEEE Directive 2012/19/EU
- UN38.3 (Battery Transport) - Electrical Safety IT/AV (IEC 62368-1)
- ISO14971:2019 (Medical Devices Risk Management)
- ISO 13485:2016 (Quality System Registered)




- IEC 62366-1 (Usability)
- IEC 62471 (Photobiological Safety – Eye tracker)
- IEC 62133/UL 2054 Battery Safety

This EU Declaration of Conformity is issued under the sole responsibility of Tobii Dynavox AB (SRN: SE-MF-000008884).

We hereby declare that the above-mentioned medical device, as described in this document, namely TD Pilot 2, including all components and accessories relevant to its intended system configuration, complies with the applicable requirements of Regulation (EU) 2017/745 on medical devices, as well as with all other applicable Union legislation listed herein.

The conformity assessment procedure has been carried out in accordance with the applicable provisions of the Regulation. All supporting technical documentation is retained at the premises of the manufacturer and is available upon request to the competent authorities.

Signed by:

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Atoosa Bayat
Global Head of Quality and Regulatory

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Date of Issue

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