



Declaration of Conformity

Tobii Dynavox AB, SRN: APP000016385, with sole responsibility as manufacturer, hereby declares that the product identified herein complies with the following directives:

EU Directives

- Regulation (EU) 2017/745 Medical Device Regulation (MDR), accessory only Article 2 (2). Class I, Rule 13
- See iPad DoC, model A2133 for 2014/53/EU, 2011/65/EU, 2009/125/EC, and relevant standards applied.

Product Information & Use

Type of product: **Speech Generating Device**

Device Identifier: **7340074601929**

Product name/Model: **TD Mobile Mini**

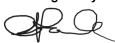
Product description: **The Mobile Mini is a small, portable, hand-held speech communication device, mainly for ambulatory, disabled, non-verbal individuals.**

Intended use: The Tobii Dynavox Mobile Mini is a speech generating device (SGD) for people who have challenges in their ability to speak due to injury, disability or illness.

The following standards have been used:

- ISO 14971:2007+2012 (Medical Device Risk Mgmt.)
- ISO 13485:2106 (Quality Management System for Medical Devices)
- IEC 60529 (Ingress Protection)
- IEC 60068-2-64, 27, 31:2008 (Shock/Vibe/Fall)

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:

9AC6C6B8A75E424...

Anthony J. Pavlik, VP of Global Operations
Signed in Pittsburgh, Pennsylvania USA

9/26/2021

Date

Tobii Dynavox AB
Box 743, S-182 17 Danderyd
Sweden
Ph: +46 8 663 69 90

Tobii Dynavox LLC
2100 Wharton Street, Suite 400
Pittsburgh PA 15203 USA
412-381-4883