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

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 13485:2016 (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.

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

Date 9/26/2021

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