tobiidynavox

CE

Declaration of Conformity

Under the sole responsibility of Tobii Dynavox, SRN SE-MF-000008884, we hereby declare that the product identified herein complies with the following directives and standards:

Medical Device Regulation (MDR) EU 2017/745, Class 1 Devices IEC 62304 Medical Device Software Lifecycle (Class A Software) IEC 62366 Application of Usability Engineering in Medical Devices CFR 21, Part 820 (cGMP) (US FDA, Class II Exempt Devices) ISO 13485:2016 (Quality System Requirements for Medical Devices)

Product Identifier (UDI/GTIN) iOS: **7340074601943** Product Identifier (UDI/GTIN) Windows: **7340074601950** Product Name: **TD Snap (formerly called Snap + CoreFirst)** Product Description: **TD Snap is an AAC/Communication Software designed for Windows based platforms, including the company's dedicated device hardware, or for iOS platforms generally for use on iPad devices.**

Intended Use: **TD Snap communication software is for people that have challenges in their ability to speak due to injury, disability or illness.**

On behalf of Tobii Dynavox AB and all of its' subsidiaries, I hereby declare that the software product named above has been designed to comply with the relevant sections of the above referenced specifications.

DocuSigned by:

Dated : December 13, 2021

Anthony J. Pavlik Chief Operating Officer Signed in Pittsburgh, Pennsylvania USA

Tobii Dynavox AB Karlsrovagen 2D Danderyd 18253 Sweden 086636990 Tobii Dynavox LLC 2100 Wharton Street, Suite 400 Pittsburgh, PA 15203 USA 412-381-4883

www.tobiidynavox.com