Declaration of Conformity

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	GoTalk Product Line
Legal Manufacturer: (Name on Label)	**Attainment Company, Inc.** 1158 Clarity St. Verona, WI 53593-0160 USA
Manufacturers SRN:	Not Yet Available
Basic UDI-DI:	08600117268GTVJ
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	To communicate in a Medical Setting
MDR Classification:	Class 1 medical device, Rule 13
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	**MT-AR-000000234**
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes I, II and III of the EU MDR 2017/745.

Name Joni Nygard **Position** Vice President AAC Resources & Services

Signed Joni Nygard **Date** 04/18/2024 **Place** Verona WI USA

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

Appendix II – Product Listing/Schedule

Catalogue Number / UDI-DI	Device Name	EMDN Code
00860011726708 00860011726715 00860011726722	GoTalk 20+ Lite Touch GoTalk 9+ Lite Touch GoTalk 4+ Lite Touch	Y214212 - Voice Generators
00860011726739 00860011726746 00860011726753 00860011726760 00860011726777 00860011726784 00860011726791	GoTalk Select GoTalk Go GoTalk Fit GoTalk Duo GoTalk One Talk Book Four GoTalk Button	Y214212 - Voice Generators
00860011726807 00860011726814	Big Button Big Button Steps and Levels	Y214212 - Voice Generators

Version History

Version	Compiled by	Date	Description
1.0	Joni Nygard	3/13/24	Initial Release
2.0	Joni Nygard	4/18/24	Amend Intended Use and Rule