

DECLARATION OF CONFORMITY

We, Prentke Romich Company, hereby declare that the below mentioned product conforms to the below mentioned regulation.

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| Manufacturer's Name and Address | Prentke Romich Company dba PRC-Salttillo 1022 Heyl Road Wooster, OH 44691 USA |
| Manufacturer's SRN (Single Registration Number) | US-MF-000018695 |
| EU Authorized Representative's Name and Address | Jürgen Babst Prentke Romich GmbH Karthäuserstr. 3 D-34117 Kassel Germany |
| EU Authorized Representative's SRN | DE-AR-000005106 |
| Type of Product: Augmentative Communication Device | Basic UDI-DI: 81648602Accent8H |
| Product Name: Accent 1000 | UDI-DI Code: 00858526006750 |
| Model Number: ACN1000-40 | |
| Conformity Assessment Route | Prentke Romich Company uses procedures for the compliance of their products according to the Regulation EU MDR 2017/745 and Directives 2014/53/EU, 2011/65/EU, and (EU) 2015/863. Class 1: EC conformity declaration according to annex VIII |
| Standards to which Conformity is Declared | |
| IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007 + AM1:2012/EN 60601-1:2006+A1:2013+A12:2014 ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012/ C1:2009/(R)2012 and A2:2010(R)2012 CAN/CSA C22.2 No. 60601-1:2014 IEC 60601-1-2:2014 IEC 60601-1-2:2015 IEC 60601-1-11:2015 EN 60601-1-11:2015 IEEE/ANSI C63.27-2017 ANSI C95.1:1992 AS/NZS 4268:2017 AS/NZS CISPR 32:2015+A1:2020 AS/NZS 62368.1:2022 FCC 47 CFR Part 15 Subpart B FCC 47 CFR Part 15 Subpart C FCC 47 CFR Part 15 Subpart E ETSI EN 300 328 V2.2.2 (2019-07) ETSI EN 300 440 V2.2.1 (2018-07) ETSI EN 301 489-1 V2.2.3 (2019-11) ETSI EN 301 489-3 V2.1.1 (2019-03) ETSI EN 301 489-17 V3.2.4 (2020-09) ETSI EN 301 893 V2.1.1 (2017-05) EN 50566:2017 EN 50663:2017 EN 55032:2015+A11:2020 BS EN 55032:2015+A11:2020 EN 55035:2017+A11:2020 | BS EN 55035:2017+A11:2020 IEC 60529:2013 EN IEC 61000-3-2:2019+A1:2021 BS EN IEC 61000-3-2:2019+A1:2021 BS EN 61000-3-3:2013+A2:2021 EN 61000-3-3:2013+A2:2021 IEC 62133-2:2017 IEC 62133-2:2017/AMD1:2021 EN IEC/IEEE 62209-1528:2021 IEC/IEEE 62209-1528 BS EN IEC 62368-1:2020+A11:2020 EN 62368-1:2020+A11:2020 IEC 62368-1:2018 RSS-102 Issue 5 February 2021 RSS-247 Issue 2 February 2017 RSS-Gen Issue 5 February 2021 AAMI TIR69 2017 IEEE 1528-2013 UN38.3 (UN Manual of Tests and Criteria ST/SG/AC.10/11/Rev.7/Amend.1/Subsection 38.3) 1999/519/EC:1999-07 ICES-003 Issue 7 KCB 248227 D01 KCB 616217 D04 KCB 447498 D04 KCB 690783 D01 KCB 865664 D01 KCB 865664 D02 |

I, the undersigned, hereby declare that the product specified above is designed to conform to the above regulation and Standards.



Dustin Welty
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Date: 16 January 2023