

DECLARATION OF CONFORMITY

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

Manufacturer's Name and Address	Prentke Romich Company dba PRC-Saltillo 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 800	UDI-DI Code: 00858526006743
Model Number: ACN800-40	
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 EU MDR 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. 60601-1:14 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 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 301 489-19 V2.2.1 (2022-09) ETSI EN 301 893 V2.1.1 (2017-05) ETSI EN 303 413 V1.2.1 (2021-04) 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 BS 61000-3-3:2013+A2:2021 IEC 62133-2:2017 IEC 62133-2:2017/AMD1:2021 EN 62209-2:2010+A1:2019 EN IEC/IEEE 62209-1528:2021 IEC/IEEE 62209-1528 BS EN IEC 62368-1:2020+A11:2020 EN IEC 62368-1:2020+A11:2020 IEC 62368-1:2018 AS/NZS 62368.1:2022 RSS-102 Issue 5 February 2021 RSS-247 Issue 2 February 2017 RSS-Gen Issue 5 March 2019 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/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
VP of Engineering
Prentke Romich Company dba PRC-Saltillo
Wooster, OH 44691 USA

Date: 16 January 2023