

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-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 1400-30	UDI-DI Code: 00858526006705
Model Number: ACN1400-30	
Conformity Assessment Route	Prentke Romich Company uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745 and Directives 2014/53/EU, 2014/35/EU, 2014/30/EU, and 2011/65/EU: Class 1: EC conformity declaration according to annex VIII
Standards to which Conformity is Declared	
IEC 60601-1:2005, COR1:2006, COR2:2007, AM1:2012	EN 300 328 V2.1.1:2016
EN 60601-1:2006+A1:2013	EN 300 330-1 V2.1.1:2017
ANSI/AAMI ES60601-1:2005/(R)2012+A1(2012)	EN 300 330-2 V2.1.1:2017
CAN/CSA C22.2 No. 60601-1:14	EN 300 440 V2.1.1:2017/EN 300 440 V2.2.1:2018
IEC 60601-1-2:2014	EN 301 489-1 V2.1.1:2017/EN 301 489-1 V2.2.0:2017
EN 60601-1-2:2015	EN 301 489-3 V2.1.1:2019/EN 301 489-3 V2.2.1:2017
IEC/EN 60601-1-11:2015	EN 301 489-17 V3.1.1:2017/EN 301 489-17 V3.2.0:2017
IEC 62133:2012/IEC 62133 CB	EN 301 489-19 V2.1.0:2017
IEC 62209-2:2010	EN 301 893 V2.1.1:2017
IEC 62368-1:2014 (Second Edition)	EN 303 413 V1.1.0:2017/EN 303 413 V1.1.1:2017
IEC 62479:2010	EN 50566:2013/EN 50566:2017
ANSI C63.27-2017	EN 50663:2017
RSS-210 + IECS003	EN 55032:2015
RSS-247 Issue 2, February 2017	EN 55035:2017
FCC Part 15 Subpart B/FCC Part 15 Subpart C/FCC Part 15 Subpart E	EN 62209-2:2010
AS/NZS 4268:2017/AS/NZS CISPR 32:2015	EN 62311:2008
EN ISO 14971:2012	EN 62368-1:2014+A11:2017
EN 61000-3-2:2014/EN 61000-3-3:2013	EN 62479:2010
EN 62209-2:2010	ICES-003 Issue 6, January 19, 2016
	IEEE/ANSI C63.27-2017/IEEE1528:2013

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



Date: 19 January 2022

Dustin Welty
VP of Engineering
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Wooster, OH 44691 USA