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: 81648602NovaChatMZ
Product Name: NovaChat	UDI-DI Code: 00816486021220
Model Number: NC10.7	
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 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, AMD1:2012 (or IEC 60601-1:2012 reprint) IEC 60601-1-2:2014+A1:2020 EN 60601-1-2:2015+A1:2021 CAN/CSA-C22.2 No. 60601-1-2:2016 (R2021) IEC 60601-1-11:2015, AMD1:2020 for use in conjunction with IEC 60601-1:2005, AMD1:2012, AMD2:2020 IEC/EN 60529: 2013 (IP44) IEC 61000-3-2:2018 IEC 61000-3-3:2013+A2:2021 EN 61000-3-2:2014 EN 61000-3-3:2013	AS/NZS 61000.3.2:2014 AS/NZS 61000.3.3:2013 AS/NZS 3200.1.2:2005 FCC CFR 47, Part 15, subpart B, Class B ICES-003, Issue 7:2020, ITE (incl. Digital Apparatus), Class B IEEE/ANSI C63.27-2017 AAMI TIR69 2017 AIM 7351731 Rev. 2.00 (2017-02-23) FDA Guidance – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices

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

Date 15 July 2022

Dustin Welty
VP of Engineering
Prentke Romich Company dba PRC-Saltillo
Wooster OH 44691 USA