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

Basic UDI-DI: 81648602NovaChatMZ

Type of Product: Augmentative Communication Device

UDI-DI Code: 00816486021381

Product Name: NovaChat

Model Number: NC8.5

Intended use: NovaChat® 8.5 is an Android™-based electronic speech generating device that augments communication for an individual with speech/language impairment. This device and its language programs give the user the power to initiate conversation, seek information, state opinions, and share feelings. It can be hand-held, used with its stand, or mounted to a wheelchair. It is accessed by using the touchscreen, a mechanical aid such as a stylus, or a variety of available switch accessories. This device does not support life. The device is not intended to be used as a sole communication aid ; it is not intended to be an emergency call device; and it is not intended to hold information critical to care of the user.

Conformity Assessment Route: Prentke Romich Company uses procedures for the compliance of their products according to the Regulation EU MDR 2017/745 and Directive 2014/53/EU.

Conformity declaration according to EU MDR Annex VIII: Class 1

Standards to which Conformity is Declared:

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021
CAN/CSA-C22.2 No. 60601-1:08
CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
IEC 60601-1-2:2014+A1:2020
EN 60601-1-2:2015+A1:2021
AS IEC 60601.1.2:2017
CAN/CSA-C22.2 No. 60601-1-2:2016 (R2021)
CAN/CSA-C22.2 No. 60601-1-2:2014, fourth edition, 2014-02
CAN/CSA-CISPR 22-10
IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 for use in conjunction with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
IEC/EN 60601-1-11:2015, AMD1:2020
CAN/CSA-C22.2 No. 60601-1-11:15
IEC/EN 60529:2013 (IP44)
IEC 61000-3-2:2020
EN 61000-3-2:2019+A1:2021
AS/NZS 61000.3.2:2013
IEC 61000-3-3:2013+A2:2021
EN 61000-3-3:2013+A1:2019
AS/NZS 61000.3.3:2012
AS/NZS 4268:2017
FCC CFR 47, Part 15, subpart B: Part 15.109(a), Class B
FCC CFR 47, Part 15, subpart B: Part 15.107(a), Class B
FCC CFR 47, Part 15, subpart C: Section 15.209
FCC 47 CFR § 2.1077 (SDoC)
ICES-003, Issue 7:2020, ITE (including Digital Apparatus), Class B
AAMI TIR69 2017
ACMA Radiocommunications (Short Range Devices) Standard 2014 – As Amended
AIM 7351731 Rev. 3.00 (2021-06-04)
ANSI C63.4:2014
IEEE/ANSI C63.27-2017
FDA Guidance – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices
FDA Guidance – Immunity to exposure to known sources of EMI

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

Date 23 May 2023

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