

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

Authorized Representative's Name and Address: Jürgen Babst
Prentke Romich GmbH
Karthäuserstr. 3
D-34117 Kassel Germany

Authorized Representative's SRN: DE-AR-000005106 **Basic UDI-DI:** 81648602iOSSGD79

Type of Product: Augmentative Communication Device **UDI-DI Code:** 00816486021350

Product Name: Via Mini **Model Number:** ViaMini8.1

Intended use: Via® Mini 8.1 is an iOS®- 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. The device can be accessed using direct selection by making physical contact with the display (e.g., fingers); direct selection aided by mechanical aids (for example, a stylus); or indirect selection by using head tracking or by using a variety of switches that enable scanning access. The unit can be hand-held, placed on a flat surface, used with a table stand, or mounted to a wheelchair. 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; The Radio Equipment Directive (RED) 2014/53/EU; RoHS Directive 2011/65/EU + (EU) 2015/863; REACH Regulation (EC) 1907/2006 and EU Waste Framework Directive (WFD) 2008/95/EC; and 768/2008/EC, Annex II, Module A(2.), (4.2).

Conformity declaration according to EU MDR Annex VIII: Class 1

Standards to which Conformity is Declared:

IEC 60601-1	EN 300 328
EN 60601-1	AS/NZS 4268:2017
ANSI AAMI ES60601-1	IEC/EN 55011
CSA C22.2 No. 60601-1	IEC/EN 60529: 2013 (IP44)
AS/NZS IEC 60601.1	IEC 61000-3-2:2020
IEC 60601-1-2:2014+A1:2020	EN 61000-3-2:2019+A1:2021
EN 60601-1-2:2015+A1:2021	IEC 61000-3-3:2013+A2:2021
CAN/CSA-C22.2 No. 60601-1-2:2016 (R2021)	EN 61000-3-3:2013+A1:2019
CAN/CSA-C22.2 No. 60601-1-2:2014, fourth edition, 2014-02, with Canadian deviations	EN 63000:2018
IEC 60601-1-11	AIM 7351731 Rev. 3.00 (2021-06-04)
IEC/EN 60601-1-11	ANSI C63.10:2020
ICES-003, Issue 7:2020 Information Technology Equipment (including Digital Apparatus), Class B	IEEE/ANSI C63.27-2017
FCC CFR 47, Part 15, Subpart B, Part 15.109(a), Class B/ Part 15.107(a), Class B	AAMI TIR69 2017
FCC Part 15, Subpart C, Section 15.247	ACMA Radiocommunications (Short Range Devices) Standard 2014 – As Amended
FCC Part 15.31(e)	KDB 447498 D04 v00
FCC Rule Part 1.1307(b)(3)(i)(a)	

I, the undersigned, hereby declare that the product specified above is designed to conform to the above regulation, directive(s), and standards.



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

Date: 7 March 2023