

# 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 **Basic UDI-DI:** 81648602IOSSGD79

**Type of Product:** Augmentative Communication Device **UDI-DI Code:** 00816486021206

**Product Name:** Via Air **Model Number:** ViaAir10.1

**Intended use:** Via® Air 10.1 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 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, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)	EN 301 489-1 V2.1.1:2017 (EMC)
AAMI/IEC 60601-1:2005 + AMD 1:2012	FCC CFR 47, Part 15, Subpart B:2017, Class B
EN 60601-1:2006 + AC:2010 and A1:2013	IEC 61000-3-2:2014 (EMC)
IEC 60601-1-2:2014+A1:2020	IEC 61000-3-3:2013 (EMC)
EN 60601-1-2:2015+A1:2021	EN 61000-3-2:2014 (EMC)
IEC 60601-1-11:2015, AMD1:2020 for use in conjunction with IEC 60601-1:2005, AMD1:2012, AMD2:2020	EN 61000-3-3:2013 (EMC)
CAN/CSA-C22.2 No. 60601-1:14	AS/NZS 61000.3.2:2014
CAN/CSA-C22.2 No. 60601-1-2:2016	AS/NZS 61000.3.3:2013
ICES-003, Issue 7:2020, Class B	AS/NZS 3200.1.2:2005, Part 1-2
EN 301 489-17 V3.2.0:2017 (EMC)	AIM 7351731 Rev. 2.00 (2017-02-23)
EN 301 489-3 V2.1.1 (2017-03) (EMC)	IEEE/ANSI C63.27-2017
	IEC/EN 60529:2013 (IP44)

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



Date: 8 March 2023

Dustin Welty  
VP of Engineering  
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