



EU Declaration of Conformity

2625 Patton Road
Roseville, MN 55113
651-294-2200
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This declaration of conformity is issued under the sole responsibility of the manufacturer. The device covered by the present declaration is in conformity with all regulations below, including compliance with related Essential Requirements.

Object of the declaration:

Product Name:	<i>iTalk4</i>
Product Model Designator:	iTalk4
Product Part Number(s):	10000028
Basic UDI-DI <required for MDR>	00186648000531
Control Indicator:	2023W01 thru 2028W01
Global Medical Device Nomenclature Code (GMDN) and Description	
Product Options/Accessories:	N/A

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The object of the declaration described above is in conformity with the following regulations:

EU Regulation	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
Device Classification:	Class I based on Annex VIII and Rule 13
Conformity Assessment Path	<i>Class I device – Self Certify – per MDR 2017/745 Annex II and III</i>
Name/Address/ID of Notified Body:	<i>Not Applicable – Class I device</i>
Standards and Common Specifications	<p>The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation and are compliant with the product standards listed below.</p> <p><i>IEC 60950-1:2005 + A1: 2009 and EN 60950-1:2006+ A11:2009 + A1:2010 + A12:2011</i> <i>BS EN ISO 14971:2019+A11:2021 – Medical Devices – Application of risk management to medical devices</i> <i>BS EN ISO 13485:2016+A11:2021 – Medical Devices – Quality management systems – Requirements for regulatory purposes</i></p>


EU Regulation	Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU
Standards and Common Specifications	<p>The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation and are compliant with the product standards listed below.</p> <p><i>CPSC-CH-E1003-09.1; CPSC-CH-E1002-08.3 and/or CPSC-CH-E1001-08.3</i></p>

EU Regulation	EMC Directive 2014/30/EU
Standards and Common Specifications	<p>The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation and are compliant with the product standards listed below.</p> <p><i>EN 60601-1-2:2015</i></p>

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Additional information:

EU Authorized Representative:	<i>EUCEREP B.V. Roald Dahllaan 33 5629MC – Eindhoven The Netherlands</i>
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Signature (signed for and on behalf of AbleNet): 	Date of Issue: <DD Month YYYY> 13 January 2023
Printed Name: Joe Volp	Place of Issue: AbleNet Inc – Roseville, MN
Title: Director of Marketing	Document Number: DoC_1000028_iTalk4 with Levels_011623