

2625 Patton Road  
Roseville, MN 55113  
800-322-0956  
www.ablenetinc.com

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:**

<b>Product Name:</b>	<i>iTalk4 with Levels</i>
<b>Product Model Designator:</b>	iTalk4 with Levels
<b>Product Part Number(s):</b>	10000028
<b>Basic UDI-DI</b> <required for MDR>	00186648000531
<b>Control Indicator:</b>	2020W20 thru 2025W20
<b>Global Medical Device Nomenclature Code (GMDN) and Description</b>	
<b>Product Options/Accessories:</b>	N/A

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

<b>EU Regulation</b>	<b>Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices</b>
<b>Device Classification:</b>	Class I based on Annex VIII and Rule 13
<b>Conformity Assessment Path</b>	<i>Not Applicable – Class I device</i>
<b>Name/Address/ID of Notified Body:</b>	<i>Not Applicable – Class I device</i>
<b>Standards and Common Specifications</b>	<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 14971:2012 – Medical Devices – Application of risk management to medical devices</i>  <i>BS EN ISO 13485:2016 – Medical Devices – Quality management systems – Requirements for regulatory purposes</i></p>
<b>EU Regulation</b>	<b>Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU</b>
<b>Standards and Common Specifications</b>	<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>Supply and Component Controls - CPSIA testing of all components. Xref testing</i></p>
<b>EU Regulation</b>	<b>EMC Directive 2014/30/EU</b>
<b>Standards and Common Specifications</b>	<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>ANSI C63.4: 2014</i></p>

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**Additional information:**

<b>EU Authorized Representative:</b>	<i>EUCEREP 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> 18 May 2020
Printed Name:  Joe Volp	Place of Issue: AbleNet Inc – Roseville, MN
Title: Director of Marketing	Document Number: DoC_1000028_iTalk4 with Levels_051820