



EU Declaration of Conformity

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

Additional Honeycomb Technologies
Building 7 Block 3 XinXing Industrial
Park, Fuyong Bao'an District, Shenzhen, China |
518103

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>Blue2 Bluetooth Switch</i>
Product Model Designator:	Blue2 Bluetooth Switch
Product Part Number(s):	10000030
Basic UDI-DI <required for MDR>	00186648000609
Control Indicator:	<ul style="list-style-type: none">• Effective 05/13/2020
Global Medical Device Nomenclature Code (GMDN) and Description	<confirm that the term is correct, active, and purchased by AbleNet>
Product Options/Accessories:	N.A.

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

Additional Honeycomb Technologies
 Building 7 Block 3 XinXing Industrial
 Park, Fuyong Bao'an District, Shenzhen, China |
 518103

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>Not Applicable – Class I device</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>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>


EU Regulation	Radio Equipment Directive (2014/53/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 62479:2010: Assessment of the compliance of low power electronic and electrical equipment</i> <i>ETSI EN 300 328 V2.1.1 (2016-11) – Wideband transmission systems</i> <i>ETSI EN 301 489-1 V2.2.0 (2017-03) – EMC standard for radio equipment and services</i> <i>Part 1</i> <i>ETSI EN 301 489-17 V3.0 (2017-03) – EMC standard for radio equipment and services</i> <i>Part 17.</i></p>

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

Additional Honeycomb Technologies
Building 7 Block 3 XinXing Industrial
Park, Fuyong Bao'an District, Shenzhen, China |
518103

Additional information:

EU Authorized Representative:	<i>EUCEREP Roald Dahllaan 33 5629MC – Eindhoven The Netherlands</i>
--------------------------------------	---

Signature (signed for and on behalf of AbleNet): 	Date of Issue: <DD Month YYYY> 13 May 2020
Printed Name: Joe Volp	Place of Issue: AbleNet Inc – Roseville, MN
Title: Director of Marketing	Document Number: DoC_10000033_Blue2_05132020