AbleNet®

EU Declaration of Conformity

2625 Patton Road
Roseville, MN 55113
651-294-2200
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:

Product Name:	*Blue2*
Product Model Designator:	Blue2
Product Part Number(s):	10000030
Basic UDI-DI *<required for MDR>*	*00186648000609*
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	*Class I device – Self Certify – per MDR 2017/745 Annex II and III*
Name/Address/ID of Notified Body:	*Not Applicable – Class I device*
Standards and Common Specifications	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. *BS EN ISO 14971:2019+A11:2021 – Medical Devices – Application of risk management to medical devices* *BS EN ISO 13485:2016+A11:2021 – Medical Devices – Quality management systems – Requirements for regulatory purposes* *IEC 60950-1:2005 (Second Edition) + Am 1:2009 + Am 2:2013;* *EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011 + A2:2013*

EU Regulation	**Radio Equipment Directive (2014/53/EU)**
Standards and Common Specifications	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. *EN 62479:2010: Assessment of the compliance of low power electronic and electrical equipment* *ETSI EN 300 328 V2.1.1 (2016-11) – Wideband transmission systems*

EU Regulation	**Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU**
Standards and Common Specifications	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. *Supply and Component Controls - CPSC-CH-E1002-08.1 and/or CPSC-CH-E1001-08.1 and CPSC-CH-C1001-09.3*

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Additional information:

EU Authorized Representative:	*EUCEREP B.V.* *Roald Dahllaan 33* *5629MC – Eindhoven* *The Netherlands*

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_10000033_Blue2_011623