

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>BIGtrack 2</i>
<b>Product Model Designator:</b>	BIGtrack 2
<b>Product Part Number(s):</b>	12000006
<b>Basic UDI-DI</b> <required for MDR>	00186648000340
<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:

EU Regulation	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
<b>Device Classification:</b>	Class I based on Annex VIII and Rule 1
<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>Information Technology Equipment - Safety IEC 60950-1:2005+A1: 2009                      EN 55022:2010+AC:2011, Class B                      CISPR 22:2008, Class B                      AS/NZS CISPR 22:2009+A1:2010, Class B                      EN 55024:2010                      IEC 61000-4-2:2008 ED.2.0                      IEC 61000-4-3:2010 ED.3.2                      IEC 61000-4-8:2009 ED.2.0</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> 13 May 2020
Printed Name:  Joe Volp	Place of Issue: AbleNet Inc – Roseville, MN
Title: Director of Marketing	Document Number: DoC_12000006_BIGtrack 2_051320