



## EU Declaration of Conformity

2625 Patton Road  
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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:

<b>Product Name:</b>	<i>BIGtrack Wireless</i>
<b>Product Model Designator:</b>	BIGtrack Wireless
<b>Product Part Number(s):</b>	10000039
<b>Basic UDI-DI</b>	00850011150054
<b>Control Indicator:</b>	2020W20 thru 2025W20
<b>Global Medical Device Nomenclature Code (GMDN) and Description</b>	
<b>Product Options/Accessories:</b>	N/A

Frölunda Data

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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 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>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)
<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>EN 62479: 2010</i>  <i>Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)</i>  <i>ETSI EN 300 328 V2.1.1 (2016-11)</i>  <i>Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU</i>  <i>ETSI EN 300 440 V2.1.1 (2017-03)</i>  <i>Short Range Devices (SRD); Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU</i>  <i>ETSI EN 301 489-1 V2.2.3 (2019-11)</i>  <i>ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility</i>  <i>ETSI EN 301 489-3 V2.1.1 (2019-03)</i></p>

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*ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU*  
*Draft ETSI EN 301 489-17 V3.2.0 (2017-03)*  
*ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU*

EU Regulation	Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU
<b>Standards and Common Specifications</b>	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.  <i>Supply and Component Controls - CPSIA testing of all components.</i>

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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> 02 June 2020
Printed Name:  Joe Volp	Place of Issue: AbleNet Inc – Roseville, MN
Title: Director of Marketing	Document Number: DoC_10000039_BIGtrackWireless_060220