



Declaration of Conformity

Product Family Name: FOCUS 5th Gen

Basic UDI-DI: 0850018342FOCUS5VK

Product Model(s): FOCUS 5-14 / FOCUS 5-40 / FOCUS 5-40 No BT & No Storage / FOCUS 5-40 No Keyboard / FOCUS 5-80 / FOCUS 5-80 No BT & No Storage

Product Risk Classification: Class I

Directive(s)/Regulation(s)/Standard(s) Applied:

MDR (EU) 2017/745	2014/53/EU RED
IEC 62368-1:2014	ESTI EN 301 489-1 V1.9.2 :2011-09
IEC 60601-1-2:2014 / EN 60601-1-2:2015 Group 1 Class B	
EN ISO 14971:2019	ESTI EN 301 489-3 V1.6.1 :2013-08
BS EN 12182:2012	ESTI EN 301 489-1 V2.1.1 :2017-02
IEC 60601-1-6:2010 + A1:2013 + A2 :2020	ESTI EN 301 489-17 V3.1.1:2017-02
EN 60601-1-6:2010 + A1:2015	
IEC 62366-1:2015 + COR1:2016	
EN 62366-1:2015 + AC:2015	
IEC 62133 IEC 62133-2:2017	ESTI EN 300 328 V2.1.1 :2016-11
EN 62133-2:2017 and UN38.3	
UL 1642, 5 th Edition	

Legal Manufacturer:

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Authorized Representative:

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I, the undersigned, hereby declare that the equipment specified herein conforms to the above Directive(s) and Regulation(s).

Name: Patrick Murphy

Title: Dir. Hardware Engineering

Signature:

Date: 05-14-2021

Place of Issue: Clearwater FL USA

Date Issued: 04-30-2021