

EU DECLARATION OF CONFORMITY **Directive 2014/53/EU**

Product Name: AVVIGO™ II Guidance System,
AVVIGO™+ Guidance System

Legal Manufacturer: Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

This declaration of conformity is issued under the sole responsibility of the manufacturer with Boston Scientific Limited, Ireland appointed as the Authorized Representative in the EU.

Objects of the declaration:

1. Tablet used in AVVIGO™ II Guidance System and AVVIGO™+ Guidance System
2. FFR Link

The objects of the declaration described above are in conformity with all relevant Union harmonization legislation of the Council Directive 2014/53/EU of 16 April 2014 concerning Radio Equipment:

The relevant harmonized standards and/or technical specifications which have been applied in relation to this declaration of conformity are:

Directive (2014/53/EU)	Standard(s) Applied in Full
Article 3.1.a (Safety)	EN 50566:2017 EN 62209-2:2010 EN 62479:2010 EN 60601-1:2006 + AM1:2013
Article 3.1.b (EMC)	EN 301 489-1 V2.2.3 EN 301 489-3 V2.1.1 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021
Article 3.2 (Spectrum)	EN 300 328 V2.2.2 EN 301 893 V2.1.1 EN 300 440 V2.2.1

The notified body SGS Fimko Ltd (Takomotie 8, FI-00380 Helsinki, Finland) issued the EU-type examination certificate RED-2140.

The following is a description of the accessories and components which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:

1. Comet Pressure Guidewire – A single use device that is used to measure intravascular pressure and deliver data to the FFR Link for processing. This device contains a passive RFID tag that is read by the RFID module when the device is inserted into the FFR Link.
2. Docking station – A docking station for the AVVIGO™ tablet to charge and connect to video and network cables
3. Power cords – A cable that is used to connect the FFR Link to hospital mains, and one to connect the AVVIGO™ tablet to hospital mains
4. Invasive Blood Pressure cable adapter - A cable that is used to allow invasive blood pressure transducers to connect to the FFR Link

Signed for and on behalf of Boston Scientific at the listed address

Erin Farrens Quality Assurance Director

Date of Issue: **July 20, 2021**