

DECLARATION OF CONFORMITY

Directive 2014/53/EU

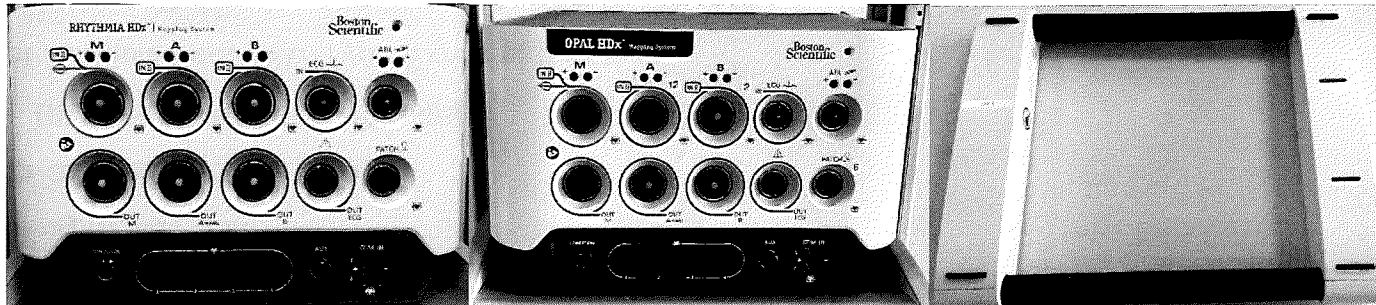
Manufacturer: Boston Scientific Corporation

Address: 300 Boston Scientific Way Marlborough, MA 01752 USA

We declare on our sole responsibility that the following radio equipment model(s) and accessories are in conformity with the relevant Union harmonisation legislation in Directive 2014/53/EU:

RHYTHMIA HDx™ MAPPING SYSTEM

OPAL HDx™ MAPPING SYSTEM



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

Concerning Article 3.1(a):

EN 60601-1-2:2015/A1:2021

Concerning Article 3.1(b):

ETSI EN 301 489-1 V2.2.3:2019

ETSI EN 301 489-3 V2.3.2:2023

EN 60601-1-2:2015/A1:2021

Concerning Article 3.2:

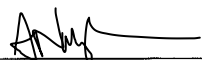
ETSI EN 303 454 V1.1.1:2018

Notified Body: Element Materials Technology

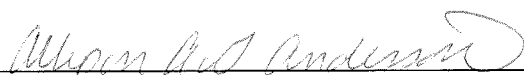
Intervention of Notified Body: EU-Type Examination

Certification Number: {Reference number of the certificate of the notified body to be entered}

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



Naughton, Alexandra -- Vice President, Quality Assurance



Allyson, Anderson -- Vice President, Research and Development

Date of Issue: 30-JAN-2025