Press Release

Date: September 18, 2019

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BIOTRONIK Obtains the World's First MDR Certification for a Class III (Highest Risk) Medical Device

The First Class III Medical Device is Certified Under the New European Medical Device Regulation

BERLIN, Germany, September 18, 2019 – BIOTRONIK today announced that it is the world's first manufacturer to receive European Medical Device Regulation (MDR) certification for a Class III (highest risk) medical device. Following a successful conformity assessment, BIOTRONIK also obtained MDR certification for its quality management system.

The MDR was introduced by the European Union (EU) with the aim to establish a modernized and more robust EU legislative framework to ensure better protection of public health and patient safety. The regulation will be fully applicable by May 2020. Over the past two and a half years, BIOTRONIK has developed a comprehensive company-wide project to manage the timely transition of all its medical devices as well as its quality management system into the new legal framework.

"The MDR brings a complete change to the regulatory framework for medical devices in Europe that emphasizes quality and safety," said Roman Borkowski, Senior Vice President Quality Management and Regulatory Affairs, Cardiac Rhythm Management at BIOTRONIK. "As a global leader in cardio- and endovascular medical technology, BIOTRONIK has a long history of commitment to quality and safety. That's why we are very proud to be the first company to demonstrate conformity to the highest MDR risk classification."

Class III medical devices represent the highest risk class of medical devices according to the MDR. Therefore, these devices are required to meet extensive clinical safety and performance requirements and undergo the highest level of device approval.

Obtaining the first MDR certificate for a Class III medical device is just the first in a series of vital steps towards MDR certification of BIOTRONIK's entire product portfolio. Mr. Borkowski commented: "With our first MDR milestone, we are pleased to have set a precedent for the future."

About BIOTRONIK
BIOTRONIK is a leading medical device company that has been developing trusted and innovative cardiovascular and endovascular solutions for more than 50 years. Driven by a purpose to perfectly match technology with the human body, BIOTRONIK innovations

deliver care that saves and improves the lives of millions diagnosed with heart and blood vessel diseases every year. BIOTRONIK is headquartered in Berlin, Germany, and represented in over 100 countries.

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