

STATEMENT

March 4, 2020

BIOTRONIK Statement on “SweynTooth” Cybersecurity Vulnerabilities

The US Food and Drug Administration has issued a [Safety Communication](#) regarding a family of cybersecurity vulnerabilities known as SweynTooth, which may introduce risks for certain medical devices that use Bluetooth Low Energy (BLE) wireless communication technology. If exploited, these vulnerabilities can allow unauthorized users to potentially cause a device to stop working, stop it from working correctly and/or bypass security to access certain device functions.

The FDA has said it is not aware of any confirmed adverse events related to these vulnerabilities although software to exploit these vulnerabilities in certain situations is already publicly available.

BIOTRONIK’s medical devices, systems and networks do not use BLE technology and are therefore not affected by the SweynTooth vulnerabilities.

Safety is paramount to the design and production of our devices and is at the center of all we do. As part of our established cybersecurity processes, we continuously analyze external reports and assess device security to ensure the safety and effectiveness of wireless technologies. We take these additional steps to support and ease the implantation and follow-up procedures for the benefit of patients and physicians.