Number: 2258950TD02

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

This certificate covers the following device(s) / groups of device(s):

Class III	
Basic UDI-DI: 0763000B00005427P Q80 DR MRI SureScan™, Q80A2, Dual Chamber (J01010302, dual-chamber implantable pacemakers with rate modulation sensor (DR)) Q70 DR MRI SureScan™, Q70A2, Dual Chamber (J01010302, dual-chamber implantable pacemakers with rate modulation sensor (DR)) G70 DR MRI SureScan™, G70A2, Dual Chamber (J01010302, dual-chamber implantable pacemakers with rate modulation sensor (DR)) Q50 DR MRI SureScan™, Q50A2, Dual Chamber (J01010302, dual-chamber implantable pacemakers with rate modulation sensor (DR)) G20 SR MRI SureScan™, G20A2, Single Chamber (J01010102, single-chamber implantable pacemakers with rate modulation sensor (SR)) Q20 SR MRI SureScan™, Q20A2, Single Chamber (J01010102, single-chamber implantable pacemakers with rate modulation sensor (SR)) **Basic UDI-DI: 0763000B00005437R** Vitatron® VSF21 Application Software, VSF21, For Programmer: 2090 and 29901 (J01900282, programming units for implantable cardiac devices - software)	Intended Purpose: Pacemakers are intended for long-term use to monitor and regulate the patient's heart rate. Pacemakers sense intrinsic electrical activity through lead electrodes, analyze heart rhythms based on programmed detection parameters, and deliver pacing pulses to treat bradyarrhythmias. The software is intended to provide information which is used to make decisions with diagnostic or therapeutic devices.

First Issued: **19 July 2022** Date: **21 October 2022** Expiry date**: 1 July 2027**

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DEKRA Certification B.V. is Notified Body with ID no 0344

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Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	19-07-2022	2007317CN92	First Issue
1	21-10-2022	2007317CN93	Revision
2			

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