

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722508 R000

Manufacturer: Biotronik AG

Address:

Ackerstrasse 6
Bülach
8180
Switzerland

Single Registration Number: CH-MF-000010176

EU Authorised Representative: BIOTRONIK SE & Co. KG

Address:

Woermannkehre 1
12359 Berlin
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme T

gulatory & Quality

First Issue Date: **2021-06-21**

Current Issue Date: **2024-05-14**

Starting Validity Date: **2024-05-14**

Expiry Date: **2026-06-20**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722508 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Orsiro Mission Sirolimus Eluting Coronary Stent System	See MDR 760568
Synsiro Pro Sirolimus Eluting Coronary Stent System	See MDR 760570
Freesolve Sirolimus Eluting Coronary Resorbable Magnesium Scaffold System	See MDR 764462
PK Papyrus Covered Coronary Stent System	See MDR 767742
Class III	Intended purpose
Pantera LEO Fast-Exchange PTCA Catheter	See MDR 722974
Pantera Pro Coronary Dilatation Catheter	See MDR 739591
Pantera Lux Paclitaxel Releasing PTCA Balloon Catheter	See MDR 767740
Passeo-18 Lux Paclitaxel releasing PTA Balloon Catheter	See MDR 767744
Class IIb, Implantable	Intended purpose
Pulsar-18 T3 Peripheral Self-Expanding Nitinol Stent System	See MDR 739593
Dynamic Renal Stent System	See MDR 784097
Dynetic-35 Peripheral Balloon-Expandable Stent System	See MDR 784098
Astron Peripheral Self-Expanding Nitinol Stent System	See MDR 784100
Pulsar-35 Peripheral Self-Expanding Nitinol Stent System	See MDR 784101

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Peripheral Balloon Catheters	Class IIa

First Issue Date: **2021-06-21**

Starting Validity Date: **2024-05-14**

Current Issue Date: **2024-05-14**

Expiry Date: **2026-06-20**

...making excellence a habit.™



EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722508 R000

Certificate History

Reference to applicable Common Specifications, Harmonized Standards, compliance with, and the relevant test and audit reports and support any of the prior certificate changes may be requested from Certificate.Verification@bsigroup.com

Date	Reference Number	Action
2021-06-21	3119775	Issued.
2021-12-16	3566636	Amended – Addition of Manufacturer Single Registration Number CH-MF-000010176. Addition of a manufacturing site for Pantera LEO sub-components and delivery systems.
2022-04-15	3656773	Supplemented – Addition of Peripheral Balloon Catheters to the Device Schedule
2022-06-01	3679069	Supplemented – Addition of Pulsar-18 T3 device to the Device Schedule
2022-12-01	3772802	Amended – Addition of Pulsar-18 T3 specific subcontractor Supplemented – Addition of Pantera Pro device to the Device Schedule Amended - Administrative update to the history. Removal of subcontractor pages
2023-06-20	3909515	Supplemented – Addition of devices: PK Papyrus Covered Coronary Stent System and Passeo-18 Lux Paclitaxel releasing PTA Balloon Catheter
2023-10-30	30001603	Supplemented – Addition of Pantera Lux Paclitaxel Releasing PTCA Balloon Catheter and Astron Peripheral Self-Expanding Nitinol Stent System devices to the Device Schedule
2023-12-18	30034841	Supplemented – Addition of Orsiro Mission Sirolimus Eluting Coronary Stent System and Synsiro Pro Sirolimus Eluting Coronary Stent System devices to the Device Schedule

First Issue Date: **2021-06-21**

Current Issue Date: **2024-05-14**

Starting Validity Date: **2024-05-14**

Expiry Date: **2026-06-20**

...making excellence a habit.™



EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722508 R000

Date	Reference Number	Action
2024-02-09	30036514	Supplemented – Addition of Freesolve Sirolimus Eluting Coronary Resorbable Magnesium Scaffold (RMS) System, Dynamic Renal Stent System, and Dynetic-35 Peripheral Balloon-Expandable Stent System devices to the Device Schedule
Current	30052329	Supplemented – Addition of Pulsar-35 Peripheral Self-Expanding Nitinol Stent System to the Device Schedule

First Issue Date: **2021-06-21**

Current Issue Date: **2024-05-14**

Starting Validity Date: **2024-05-14**

Expiry Date: **2026-06-20**

...making excellence a habit.™