EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735427 R000

Manufacturer: Abbott Medical

Address:
3200 Lakeside Drive
Santa Clara
California
95054
USA

Single Registration Number: US-MF-000003851

EU Authorised Representative: Abbott Vascular International BVBA

Address:
Park Lane, Culliganlaan 2B
1831 Diegem
Belgium

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-12-01**

Current Issue Date: **2024-01-23**

Starting Validity Date: **2024-01-23**

Expiry Date: **2026-11-30**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735427 R000

Device Schedule:

Device Name: XIENCE PRO 48 Everolimus Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
The XIENCE PRO 48 Everolimus Eluting Coronary Stent System is intended to improve coronary artery luminal diameter.

Risk Classification: Class III Implantable

Basic UDI-DI: 8717648DES0001TC

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]
	48
2.5	1017250-48
2.75	1017275-48
3.0	1017300-48
3.5	1017350-48

First Issue Date: **2021-12-01**

Current Issue Date: **2024-01-23**

Starting Validity Date: **2024-01-23**

Expiry Date: **2026-11-30**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735427 R000

Device Name: XIENCE PRO^{A} Everolimus Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
The XIENCE PRO^{A} Everolimus Eluting Coronary Stent System is intended to improve coronary artery luminal diameter.

Risk Classification: Class III Implantable

Basic UDI-DI: 8717648DES0001TC

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]							
	8	12	15	18	23	28	33	38
2.0	1128200-08	1128200-12	1128200-15	1128200-18	1128200-23	1128200-28	--	--
2.25	1128225-08	1128225-12	1128225-15	1128225-18	1128225-23	1128225-28	--	--
2.5	1128250-08	1128250-12	1128250-15	1128250-18	1128250-23	1128250-28	1128250-33	1128250-38
2.75	1128275-08	1128275-12	1128275-15	1128275-18	1128275-23	1128275-28	1128275-33	1128275-38
3.0	1128300-08	1128300-12	1128300-15	1128300-18	1128300-23	1128300-28	1128300-33	1128300-38
3.25	1128325-08	1128325-12	1128325-15	1128325-18	1128325-23	1128325-28	1128325-33	1128325-38
3.5	1128350-08	1128350-12	1128350-15	1128350-18	1128350-23	1128350-28	1128350-33	1128350-38
4.0	1128400-08	1128400-12	1128400-15	1128400-18	1128400-23	1128400-28	1128400-33	1128400-38

First Issue Date: **2021-12-01**

Current Issue Date: **2024-01-23**

Starting Validity Date: **2024-01-23**

Expiry Date: **2026-11-30**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735427 R000

Device Name: XIENCE PRO^{S} Everolimus Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:

The XIENCE PRO^{S} Everolimus Eluting Coronary Stent System is intended to improve coronary artery luminal diameter.

Risk Classification: Class III Implantable

Basic UDI-DI: 8717648DES0001TC

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]							
	8	**12**	**15**	**18**	**23**	**28**	**33**	**38**
2.0	1508200-08	1508200-12	1508200-15	1508200-18	1508200-23	1508200-28	1508200-33	1508200-38
2.25	1508225-08	1508225-12	1508225-15	1508225-18	1508225-23	1508225-28	1508225-33	1508225-38
2.5	1508250-08	1508250-12	1508250-15	1508250-18	1508250-23	1508250-28	1508250-33	1508250-38
2.75	1508275-08	1508275-12	1508275-15	1508275-18	1508275-23	1508275-28	1508275-33	1508275-38
3.0	1508300-08	1508300-12	1508300-15	1508300-18	1508300-23	1508300-28	1508300-33	1508300-38
3.25	1508325-08	1508325-12	1508325-15	1508325-18	1508325-23	1508325-28	1508325-33	1508325-38
3.5	1508350-08	1508350-12	1508350-15	1508350-18	1508350-23	1508350-28	1508350-33	1508350-38
4.0	1508400-08	1508400-12	1508400-15	1508400-18	1508400-23	1508400-28	1508400-33	1508400-38

First Issue Date: **2021-12-01**

Current Issue Date: **2024-01-23**

Starting Validity Date: **2024-01-23**

Expiry Date: **2026-11-30**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735427 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-12-01	3281083	Issued.
Current	30003737	Amended – Add alternate Tyvek coatings for packaging pouch.

First Issue Date: **2021-12-01**

Current Issue Date: **2024-01-23**

Starting Validity Date: **2024-01-23**

Expiry Date: **2026-11-30**

...making excellence a habit.™