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Location: Moldova

Certificate ES15/17244

The management system of

LIFE VASCULAR DEVICES BIOTECH, S.L. also trading as LVD BIOTECH, S.L.

Camí de Can Ubach 11, Polígono Industrial Les Fallulles
08620 Sant Vicenç dels Horts, Barcelona. Spain

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 08 March 2019 until 08 March 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 12 December 2021
Issue 4. Certified since 16 January 2015

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

LIFE VASCULAR DEVICES BIOTECH, S.L. also trading as LVD BIOTECH, S.L.

ISO 13485:2016
EN ISO 13485:2016

Issue 4

Detailed scope

Design and development, manufacture and distribution of sterile percutaneous device for treatment of vascular disease and non-active sterile vascular implants.

Design and development, manufacturing and distribution of polymer-based coatings and application technology for interventional catheters with limited exposure (⩽ 24 h).

Design and development, manufacture and distribution of high-precision plastic tubing for medical applications.

Diseño, desarrollo, fabricación y distribución de dispositivos estériles percutáneos para el tratamiento de enfermedades vasculares e implantes vasculares estériles no actives

Diseño y desarrollo, fabricación y distribución de recubrimientos poliméricos y de la tecnología de aplicación para catéteres intervencionista de exposición limitada (≤ 24 h).

Diseño y desarrollo, fabricación y distribución de tubos de plástico de alta precisión para aplicaciones médicas

UKAS MANAGEMENT SYSTEMS
0005

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo II (excepto punto 4) de la Directiva 93/42/CEE
EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex II (except Section 4) of Directive 93/42/EEC

Certificado nº/*Certificate no*		Fecha de validez/*Date of validity*			ON nº/*NB no*
2013 07 0801 CT	**Desde/*From***	**31-07-2020**	**Hasta/*To***	**26-05-2024**	**0318**

A favor de/*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name*: **LIFE VASCULAR DEVICES BIOTECH S.L. (LVD BIOTECH)**
Dirección/*Address*: Camí de Can Ubach, 11; Pol. Ind. Les Fallulles
08620 Sant Vicenç dels Horts- Barcelona-ESPAÑA
Representante autorizado ante la UE/*Authorized EU representative*: Idem

Para el producto/*For the product*:

Categoría/*Category*: Productos sanitarios implantables no activos/*Non-active implantable medical devices*
Grupo genérico/ *Generic group*: Especificado en Anexos de este Certificado/Specified in Annexes to this Certificate/*Haga clic o pulse aquí para escribir texto.*
Tipo/*Type*: Especificado en Anexos de este Certificado/*Specified in Annexes to this Certificate*

Elaborado en/*In the facilities*:

Camí de Can Ubach, 11; Pol. Ind. Les Fallulles , 08620 Sant Vicenç dels Horts- Barcelona-ESPAÑA

Fecha inicial/ *Initial date:* 3 -07-2013
Fecha de prórroga anterior/ *Previous extension date:* 21-07-2017

Este certificado debe ir acompañado por certificado de examen de diseño: en productos de clase III /*This certificate must be accompanied by design examination certificate*: in class III products
Este certificado es consecuencia de la auditoria del sistema completo de garantía de calidad y del examen de la documentación técnica contenida en el expediente nº 2012 01 0327, y garantiza que los productos descritos cumplen los requisitos de la Directiva./ *This certificate is issued on the full quality assurance system audit, and the examination of the technical documentation contained in dossier nº 2012 01 0327, and guarantees that the described products fulfils the requirements of the Directive*

MODELO-1P ANEXO II CT Cert. 93/42/1P-Rev.1805/2020

Madrid, 29 de julio de 2020
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
Fecha de la firma: 29/07/2020
Puede comprobar la autenticidad del documento en la sede de la AEMPS:https://localizador.aemps.es
CSV: B V E J Q Y 5 9 7 B

ANEXO Nº/*ANNEX NO:* I

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Fabricante/*Manufacturer*:
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Dirección/*Address*: Camí de Can Ubach, 11; Pol. Ind. Les Fallulles
08620 Sant Vicenç dels Horts- Barcelona-ESPAÑA
Representante autorizado ante la UE/*Authorized EU representative*: Idem

Tipo de producto / *Devices type*: Los relacionados a continuación/*The list below*

Clasificación/*Classification:* IIb

1. **Sistema de stent periférico** / *Peripheral stent system* **Código NANDO: MD 0201 y MDS 7006**

1.1. Sistema de stent periférico CoCr para guía de 0.035" "iVascular restorer"/ *"iVascular restorer" Peripheral CoCr stent system for 0.035" guidewire*

1.1.a. Longitud de catéter 80cm/ *Catheter length 80cm*

- **1.1.a.1. Stent 5.0 x 18mm/** *Stent 5.0 x 18mm*
- **1.1.a.2. Stent 5.0 x 28mm/** *Stent 5.0 x 28mm*
- **1.1.a.3. Stent 5.0 x 38mm/** *Stent 5.0 x 38mm*
- **1.1.a.4. Stent 5.0 x 58mm/***Stent 5.0 x 58mm*
- **1.1.a.5. Stent 6.0 x 18mm/***Stent 6.0 x 18mm*
- **1.1.a.6. Stent 6.0 x 28mm/** *Stent 6.0 x 28mm*
- **1.1.a.7. Stent 6.0 x 38mm/***Stent 6.0 x 38mm*
- **1.1.a.8. Stent 6.0 x 58mm/***Stent 6.0 x 58mm*
- **1.1.a.9. Stent 7.0 x 18mm/** *Stent 7.0 x 18mm*
- **1.1.a.10. Stent 7.0 x 28mm/** *Stent 7.0 x 28mm*
- **1.1.a.11. Stent 7.0 x 38mm/** *Stent 7.0 x 38mm*
- **1.1.a.12. Stent 7.0 x 58mm/** *Stent 7.0 x 58mm*
- **1.1.a.13. Stent 8.0 x 18mm/** *Stent 8.0 x 18mm*
- **1.1.a.14. Stent 8.0 x 28mm/** *Stent 8.0 x 28mm*
- **1.1.a.15. Stent 8.0 x 38mm/** *Stent 8.0 x 38mm*

1.1.a.16. Stent 8.0 x 58mm/ *Stent 8.0 x 58mm*
1.1.a.17. Stent 9.0 x 18mm/ *Stent 9.0.x 18mm*
1.1.a.18. Stent 9.0 x 28mm/ *Stent 9.0.x 28mm*
1.1.a.19. Stent 9.0 x 38mm/ *Stent 9.0 x 38.mm*
1.1.a.20. Stent 9.0 x 58mm/ *Stent 9.0 x 58mm*
1.1.a.21. Stent 10.0 x 18mm/ *Stent 10.0 x 18mm*
1.1.a.22. Stent 10.0 x 28mm/ *Stent 10.0 x 28mm*
1.1.a.23. Stent 10.0 x 38mm/ *Stent 10.0 x 38mm*
1.1.a.24. Stent 10.0 x 58mm/ *Stent 10.0 x 58mm*

1.1.b Longitud de catéter 140cm/ *Catheter length 140cm*

1.1.b.1 Stent 5.0 x 18mm/ *Stent 5.0 x 18mm*
1.1.b.2 Stent 5.0 x 28mm/ *Stent 5.0 x 28mm*
1.1.b.3 Stent 5.0 x 38mm/ *Stent 5.0 x 38mm*
1.1.b.4 Stent 5.0 x 58mm/*Stent 5.0 x 58mm*
1.1.b.5 Stent 6.0 x 18mm/*Stent 6.0 x 18mm*
1.1.b.6 Stent 6.0 x 28mm/ *Stent 6.0 x 28mm*
1.1.b.7 Stent 6.0 x 38mm/*Stent 6.0 x 38mm*
1.1.b.8 Stent 6.0 x 58mm/*Stent 6.0 x 58mm*
1.1.b.9 Stent 7.0 x 18mm/ *Stent 7.0 x 18mm*
1.1.b.10 Stent 7.0 x 28mm/ *Stent 7.0 x 28mm*
1.1.b.11 Stent 7.0 x 38mm/ *Stent 7.0 x 38mm*
1.1.b.12 Stent 7.0 x 58mm/ *Stent 7.0 x 58mm*
1.1.b.13 Stent 8.0 x 18mm/ *Stent 8.0 x 18mm*
1.1.b.14 Stent 8.0 x 28mm/ *Stent 8.0 x 28mm*
1.1.b.15 Stent 8.0 x 38mm/ *Stent 8.0 x 38mm*
1.1.b.16 Stent 8.0 x 58mm/ *Stent 8.0 x 58mm*
1.1.b.17 Stent 9.0 x 18mm/ *Stent 9.0 x 18mm*

1.1.b.18 Stent 9.0 x 28mm/ *Stent 9.0 x 28mm*
1.1.b.19 Stent 9.0 x 38mm/ *Stent 9.0 x 38mm*
1.1.b.20 Stent 9.0 x 58mm/ *Stent 9.0 x 58mm*
1.1.b.21 Stent 10.0 x 18mm/ *Stent 10.0 x 18mm*
1.1.b.22 Stent 10.0 x 28mm/ *Stent 10.0 x 28mm*
1.1.b.23 Stent 10.0 x 38mm/ *Stent 10.0 x 38mm*
1.1.b.24 Stent 10.0x 58mm/ *Stent 10. 0x 58mm*

2. Sistema de stent periférico autoexpandible/ *Self expanding peripheral stent system*

2.1. Sistema de stent periférico autoexpandible NiTi para guía de 0.035" "iVascular iVolution" / *"iVascular iVolution" NiTi self expanding peripheral stent system for 0.035" guidewire*

1.1.a. Longitud de catéter 80cm/ *Catheter length 80cm*
1.1.a.1. Stent 5.0 x 40mm/ *Stent 5.0 x 40mm*
1.1.a.2. Stent 5.0 x 60mm/ *Stent 5.0 x 60mm*
1.1.a.3. Stent 5.0 x 80mm/ *Stent 5.0 x 80mm*
1.1.a.4. Stent 5.0 x100mm/*Stent 5.0 x 100mm*
1.1.a.5. Stent 5.0 x 150mm/ *Stent 5.0 x 150mm*
1.1.a.6. Stent 5.0 x 200mm/*Stent 5.0 x 200mm*
1.1.a.7. Stent 6.0 x 40mm/*Stent 6.0 x 40mm*
1.1.a.8. Stent 6.0 x 60mm/ *Stent 6.0 x 60mm*
1.1.a.9. Stent 6.0 x 80mm/*Stent 6.0 x 80mm*
1.1.a.10. Stent 6.0 x 100mm/*Stent 6.0 x 100mm*
1.1.a.11. Stent 6.0 x 150mm/ *Stent 6.0 x 150mm*
1.1.a.12. Stent 6.0 x 200mm/*Stent 6.0 x 200mm*
1.1.a.13. Stent 7.0 x 40mm/ *Stent 7.0 x 40mm*
1.1.a.14. Stent 7.0 x 60mm/ *Stent 7.0.x 60mm*
1.1.a.15. Stent 7.0 x 80mm/ *Stent 7.0 x 80mm*

1.1.a.16. Stent 7.0 x 100mm/ *Stent 7.0 x 100mm*
1.1.a.17. Stent 7.0 x 150mm/ *Stent 7.0 x 150mm*
1.1.a.18. Stent 7.0 x 200mm/*Stent 7.0 x 200mm*
1.1.a.19. Stent 8.0 x 40mm/ *Stent 8.0 x 40mm*
1.1.a.20. Stent 8.0 x 60mm/ *Stent 8.0 x 60mm*
1.1.a.21. Stent 8.0 x 80mm/ *Stent 8.0 x 80mm*
1.1.a.22. Stent 8.0 x 100mm/ *Stent 8.0 x 100mm*
1.1.a.23. Stent 8.0 x 150mm/ *Stent 8.0 x 150mm*
1.1.a.24. Stent 9.0 x 40mm/ *Stent 9.0 x 40mm*
1.1.a.25. Stent 9.0 x 60mm/ *Stent 9.0 x 60mm*
1.1.a.26. Stent 9.0 x 80mm/ *Stent 9.0 x 80mm*
1.1.a.27. Stent 9.0 x 100mm/ *Stent 9.0 x 100mm*
1.1.a.28. Stent 10.0 x 40mm/ *Stent 10.0 x 40mm*
1.1.a.29. Stent 10.0 x 60mm/ *Stent 10.0 x 60mm*
1.1.a.30. Stent 10.0 x 80mm/ *Stent 10.0 x 80mm*
1.1.a.31. Stent 10.0 x 100mm/ *Stent 10.0 x 100mm*

2.1.b. Longitud de catéter 140cm/ *Catheter length 140cm*

2.1.b.1 Stent 5.0 x 40mm/ *Stent 5.0 x 40mm*
2.1.b.2 Stent 5.0 x 60mm/ *Stent 5.0 x 60mm*
2.1.b.3 Stent 5.0 x 80mm/ *Stent 5.0 x 80mm*
2.1.b.4 Stent 5.0 x 100mm/*Stent 5.0 x 100mm*
2.1.b.5 Stent 5.0 x 150mm/ *Stent 5.0 x 150mm*
2.1.b.6 Stent 5.0 x 200mm/*Stent 5.0 x 200mm*
2.1.b.7 Stent 6.0 x 40mm/*Stent 6.0 x 40mm*
2.1.b.8 Stent 6.0 x 60mm/ *Stent 6.0 x 60mm*
2.1.b.9 Stent 6.0 x 80mm/*Stent 6.0 x 80mm*
2.1.b.10 Stent 6.0 x 100mm/*Stent 6.0 x 100mm*

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2.1.b.11 **Stent 6.0 x 150mm/** *Stent 6.0 x 150mm*
2.1.b.12 **Stent 6.0 x 200mm/***Stent 6.0 x 200mm*
2.1.b.13 **Stent 7.0 x 40mm/** *Stent 7.0 x 40mm*
2.1.b.14 **Stent 7.0 x 60mm/** *Stent 7.0 x 60mm*
2.1.b.15 **Stent 7.0 x 80mm/** *Stent 7.0 x 80mm*
2.1.b.16 **Stent 7.0 x 100mm/** *Stent 7.0 x 100mm*
2.1.b.17 **Stent 7.0 x 150mm/** *Stent 7.0 x 150mm*
2.1.b.18 **Stent 7.0 x 200mm/***Stent 7.0 x 200mm*
2.1.b.19 **Stent 8.0 x 40mm/** *Stent 8.0 x 40mm*
2.1.b.20 **Stent 8.0 x 60mm/** *Stent 8.0 x 60mm*
2.1.b.21 **Stent 8.0 x 80mm/** *Stent 8.0 x 80mm*
2.1.b.22 **Stent 8.0 x 100mm/** *Stent 8.0 x 100mm*
2.1.b.23 **Stent 8.0 x 150mm/** *Stent 8.0 x 150mm*
2.1.b.24 **Stent 9.0 x 40mm/** *Stent 9.0 x 40mm*
2.1.b.25 **Stent 9.0 x 60mm/** *Stent 9.0 x 60mm*
2.1.b.26 **Stent 9.0 x 80mm/** *Stent 9.0 x 80mm*
2.1.b.27 **Stent 9.0 x 100mm/** *Stent 9.0 x 100mm*
2.1.b.28 **Stent 10.0 x 40mm/** *Stent 10.0 x 40mm*
2.1.b.29 **Stent 10.0 x 60mm/** *Stent 10.0 x 60mm*
2.1.b.30 **Stent 10.0 x 80mm/** *Stent 10.0 x 80mm*
2.1.b.31 **Stent 10.0 x 100mm/** *Stent 10.0 x 100mm*

2.2 Sistema de stent periférico autoexpandible NiTi para guía de 0.035", iVascular iVolution pro / *iVascular iVolution pro, NiTi self expanding peripheral stent system for 0.035" guidewire*

2.2.a Longitud de catéter 80cm/ *Catheter length 80cm*
2.2.a 1 **Stent 5.0 x 40mm/** *Stent 5.0 x 40mm*
2.2.a.2 **Stent 5.0 x 60mm/** *Stent 5.0 x 60mm*
2.2.a.3 **Stent 5.0 x 80mm/** *Stent 5.0 x 80mm*

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2.2.a.4 Stent 5.0 x 100mm/*Stent 5.0 x 100mm*
2.2.a.5 Stent 5.0 x 150mm/ *Stent 5.0 x 150mm*
2.2.a.6 Stent 5.0 x 200mm/*Stent 5.0 x 200mm*
2.2.a.7 Stent 6.0 x 40mm/*Stent 6.0 x 40mm*
2.2.a.8 Stent 6.0 x 60mm/ *Stent 6.0 x 60mm*
2.2.a.9 Stent 6.0 x 80mm/*Stent 6.0 x 80mm*
2.2.a.10 Stent 6.0 x 100mm/*Stent 6.0 x 100mm*
2.2.a.11 Stent 6.0 x 150mm/ *Stent 6.0 x150mm*
2.2.a.12 Stent 6.0 x 200mm/*Stent 6.0 x 200mm*
2.2.a.13 Stent 7.0 x 40mm/ *Stent 7.0 x 40mm*
2.2.a.14 Stent 7.0 x 60mm/ *Stent 7.0 x 60mm*
2.2.a 15 Stent 7.0 x 80mm/ *Stent 7.0 x 80mm*
2.2.a.16 Stent 7.0 x 100mm/ *Stent 7.0 x 100mm*
2.2.a.17 Stent 7.0 x 150mm/ *Stent 7.0 x 150mm*
2.2.a.18 Stent 7.0 x 200mm/*Stent 7.0 x 200mm*
2.2.a.19 Stent 8.0 x 40mm/ *Stent 8.0 x 40mm*
2.2.a 20 Stent 8.0 x 60mm/ *Stent 8.0 x 60mm*
2.2.a.21 Stent 8.0 x 80mm/ *Stent 8.0 x 80mm*
2.2.a.22 Stent 8.0 x 100mm/ *Stent 8.0 x 100mm*
2.2.a.23 Stent 8.0 x 150mm/ *Stent 8.0 x 150mm*
2.2.a.24 Stent 9.0 x 40mm/ *Stent 9.0 x 40mm*
2.2.a.25 Stent 9.0 x 60mm/ *Stent 9.0 x 60mm*
2.2.a.26 Stent 9.0 x 80mm/ *Stent 9.0 x 80mm*
2.2.a.27 Stent 9.0 x 100mm/ *Stent 9.0 x 100mm*
2.2.a.28 Stent 10.0 x 40mm/ *Stent 10.0 x 40mm*
2.2.a.29 Stent 10.0 x 60mm/ *Stent 10.0 x 60mm*
2.2.a.30 Stent 10.0 x 80mm/ *Stent 10.0 x 80mm*
2.2.a.31 Stent 10.0 x 100mm/ *Stent 10.0 x 100mm*

CORREO ELECTRÓNICO
on0318@aemps.es

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28022 MADRID
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2.2.b. Longitud de catéter 130cm/ *Catheter length 130cm*

2.2.b.1 Stent 5.0 x 40mm/ *Stent 5.0 x 40mm*
2.2.b.2 Stent 5.0 x 60mm/ *Stent 5.0 x 60mm*
2.2.b.3 Stent 5.0 x 80mm/ *Stent 5.0 x 80mm*
2.2.b.4 Stent 5.0 x 100mm/*Stent 5.0 x 100mm*
2.2.b.5 Stent 5.0 x 150mm/ *Stent 5.0 x 150mm*
2.2.b.6. Stent 5.0 x 200mm/*Stent 5.0 x 200mm*
2.2.b.7 Stent 6.0 x 40mm/*Stent 6.0 x 40mm*
2.2.b.8 Stent 6.0 x 60mm/ *Stent 6.0 x 60mm*
2.2.b.9 Stent 6.0 x 80mm/*Stent 6.0 x 80mm*
2.2.b.10 Stent 6.0 x 100mm/*Stent 6.0 x 100mm*
2.2.b.11 Stent 6.0 x 150mm/ *Stent 6.0 x 150mm*
2.2.b.12 Stent 6.0 x 200mm/*Stent 6.0 x 200mm*
2.2.b.13 Stent 7.0 x 40mm/ *Stent 7.0 x 40mm*
2.2.b.14 Stent 7.0 x 60mm/ *Stent 7.0 x 60mm*
2.2.b.15 Stent 7.0 x 80mm/ *Stent 7.0 x 80mm*
2.2.b.16 Stent 7.0 x 100mm/ *Stent 7.0 x 100mm*
2.2.b.17 Stent 7.0 x 150mm/ *Stent 7.0 x 150mm*
2.2.b.18 Stent 7.0 x 200mm/*Stent 7.0 x 200mm*
2.2.b.19 Stent 8.0 x 40mm/ *Stent 8.0 x 40mm*
2.2.b.20 Stent 8.0 x 60mm/ *Stent 8.0 x 60mm*
2.2.b.21 Stent 8.0 x 80mm/ *Stent 8.0 x 80mm*
2.2.b.22 Stent 8.0 x 100mm/ *Stent 8.0 x 100mm*
2.2.b.23 Stent 8.0 x 150mm/ *Stent 8.0 x 150mm*
2.2.b.24 Stent 9.0 x 40mm/ *Stent 9.0 x 40mm*
2.2.b.25 Stent 9.0 x 60mm/ *Stent 9.0 x 60mm*
2.2.b.26 Stent 9.0 x 80mm/ *Stent 9.0 x 80mm*
2.2.b.27 Stent 9.0 x 100mm/ *Stent 9.0 x 100mm*

CORREO ELECTRÓNICO
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ORGANISMO NOTIFICADO 0318

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2.2.b.28 Stent 10.0 x 40mm/ *Stent 10.0 x 40mm*
2.2.b.29 Stent 10.0 x 60mm/ *Stent 10.0 x 60mm*
2.2.b.30 Stent 10.0 x 80mm/ *Stent 10.0 x 80mm*
2.2.b.31 Stent 10.0 x 100mm/ *Stent 10.0 x 100mm*

Clasificación/Classification: III

3. Sistema de stent coronario */ Coronary stent system* **Código NANDO: MD 0201 y MDS 7006**

3.1. Sistema de stent coronario CoCr "iVascular architect*"/"iVascular architect" CoCr coronary stent system*

Los siguientes productos se encuentran descritos en el certificado 2013 03 0797 ED/ *The followed products are described in the certificate 2013 03 0797 ED.*

3.1.a. Longitud de catéter 142cm/ *Catheter length 142cm*
3.1.a.1 Stent 2.0 x 9mm/ *Stent 2.0 x 9mm*
3.1.a.2 Stent 2.0 x 14mm/ *Stent 2.0 x 14mm*
3.1.a.3 Stent 2.0 x 16mm/ *Stent 2.0 x16mm*
3.1.a.4 Stent 2.0 x 19mm/ *Stent 2.0 x 19mm*
3.1.a.5 Stent 2.0 x 24mm/.*Stent 2.0 x 24mm*
3.1.a.6 Stent 2.0 x 29mm/.*Stent 2.0 x 29mm*
3.1.a.7 Stent 2.0 x 34mm/ *Stent 2.0 x 34mm*
3.1.a.8 Stent 2.0 x 39mm/ *Stent 2.0 x 39mm*
3.1.a.9 Stent 2.25 x 9mm/ *Stent 2.25 x 9mm*
3.1.a.10 Stent 2.25 x 14mm/ *Stent 2.25 x 14mm*
3.1.a.11 Stent 2.25 x 16mm/ *Stent 2.25 x 16mm*
3.1.a.12 Stent 2.25 x 19mm/ *Stent 2.25 x 19mm*
3.1.a.13 Stent 2.25 x 24mm/ *Stent 2.25 x 24mm*
3.1.a.14 Stent 2.25 x 29mm/ *Stent 2.25 x 29mm*
3.1.a.15 Stent 2.25 x 34mm/ *Stent 2.25 x 34mm*
3.1.a.16 Stent 2.25 x 39mm/ *Stent 2.25 x 39mm*

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo II (excepto punto 4) de la Directiva 93/42/CEE

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex II (except Section 4) of Directive 93/42/EEC

Certificado nº/*Certificate no*		Fecha de validez/*Date of validity*			ON nº/*NB no*
2013 07 0801 CT	**Desde/*From***	**31-07-2020**	**Hasta/*To***	**26-05-2024**	**0318**

3.1.a.17 Stent 2.5 x 9mm/ *Stent 2.5 x 9mm*
3.1.a.18 Stent 2.5 x 14mm/ *Stent 2.5 x 14mm*
3.1.a.19 Stent 2.5 x 16mm/ *Stent 2.5 x 16mm*
3.1.a.20 Stent 2.5 x 19mm/ *Stent 2.5 x 19mm*
3.1.a.21 Stent 2.5 x 24mm/ *Stent 2.5 x 24mm*
3.1.a.22 Stent 2.5 x 29mm/ *Stent 2.5 x 29mm*
3.1.a.23 Stent 2.5 x 34mm/ *Stent 2.5 x 34mm*
3.1.a.24 Stent 2.5 x 39mm/ *Stent 2.5 x 39mm*
3.1.a.25 Stent 2.75 x 9mm/ *Stent 2.75 x 9mm*
3.1.a.26 Stent 2.75 x 14mm/ *Stent 2.75 x 14mm*
3.1.a.27 Stent 2.75 x 16mm/ *Stent 2.75 x 16mm*
3.1.a.28 Stent 2.75 x 19mm/ *Stent 2.75 x 19mm*
3.1.a.29 Stent 2.75 x 24mm/ *Stent 2.75 x 24mm*
3.1.a.30 Stent 2.75 x 29mm/ *Stent 2.7 5x 29mm*
3.1.a.31 Stent 2.75 x 34mm/ *Stent 2.75 x 34mm*
3.1.a.32 Stent 2.75 x 39mm/ *Stent 2.75 x 39mm*
3.1.a.33 Stent 3.0 x 9mm/ *Stent 3.0 x 9mm*
3.1.a.34 Stent 3.0 x 14mm/ *Stent 3.0 x 14mm*
3.1.a.35 Stent 3.0 x 16mm/ *Stent 3.0 x 16mm*
3.1.a.36 Stent 3.0 x 19mm/ *Stent 3.0 x 19mm*
3.1.a.37 Stent 3.0 x 24mm/ *Stent 3.0 x 24mm*
3.1.a.38 Stent 3.0 x 29mm/ *Stent 3.0 x 29mm*
3.1.a.39 Stent 3.0 x 34mm/ *Stent 3.0 x34mm*
3.1.a.40 Stent 3.0 x 39mm/ *Stent 3.0 x 39mm*
3.1.a.41 Stent 3.5 x 9mm/ *Stent 3.5 x 9mm*
3.1.a.42 Stent 3.5 x 14mm/ *Stent 3.5 x 14mm*
3.1.a.43 Stent 3.5 x 16mm/ *Stent 3.5 x 16mm*
3.1.a.44 Stent 3.5 x 19mm/ *Stent 3.5 x 19mm*
3.1.a.45 Stent 3.5 x 24mm/ *Stent 3.5 x 24mm*
3.1.a.46 Stent 3.5 x 29mm/ *Stent 3.5 x 29mm*
3.1.a.47 Stent 3.5 x 34mm/ *Stent 3.5 x 34mm*
3.1.a.48 Stent 3.5 x 39mm/ *Stent 3.5 x 39mm*

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3.1.a.49 Stent 4.0 x 9mm/ *Stent 4.0 x 9mm*
3.1.a.50 Stent 4.0 x 14mm/ *Stent 4.0 x 14mm*
3.1.a.51 Stent 4.0 x 16mm/ *Stent 4.0 x 16mm*
3.1.a.52 Stent 4.0 x 19mm/ *Stent 4.0 x 19mm*
3.1.a.53 Stent 4.0 x 24mm/ *Stent 4.0 x 24mm*
3.1.a.54 Stent 4.0 x 29mm/ *Stent 4.0 x 29mm*
3.1.a.55 Stent 4.0 x 34mm/ *Stent 4.0 x 34mm*
3.1.a.56 Stent 4.0 x 39mm/ *Stent 4.0 x 39mm*
3.1.a.57 Stent 4.5 x 14mm/ *Stent 4.5 x 14mm*
3.1.a.58 Stent 4.5 x 16mm/ *Stent 4.5 x 16mm*
3.1.a.59 Stent 4.5 x 19mm/ *Stent 4.5 x 19mm*
3.1.a.60 Stent 4.5 x 24mm/ *Stent 4.5 x 24mm*
3.1.a.61 Stent 4.5 x 29mm/ *Stent 4.5 x 29mm*
3.1.a.62 Stent 4.5 x 34mm/*Stent 4.5 x 34mm*
3.1.a.63 Stent 4.5 x 39mm/ *Stent 4.5 x 39mm*

4. Sistema de stent coronario con liberación de sirolimus / *Sirolimus eluting coronary stent system*

Código NANDO: MD 0201, MDS 7001 y MDS 7006

4.1. Sistema de stent coronario con liberación de sirolimus, con stent de CoCr y polímero bioestable "iVascular angiolite*"/"iVascular angiolite" Sirolimus eluting coronary stent system,with CoCr stent and permanent polymer*

Los siguientes productos se encuentran descritos en el certificado 2014 12 0833 ED/ *The followed products are described in the certificate 2014 12 0833 ED.*

4.1.a. Longitud de catéter 142cm/ Catheter length 142cm
4.1.a.1 Stent 2.0 x 9mm/ *Stent 2.0 x 9mm*
4.1.a.2 Stent 2.0 x 14mm/ *Stent 2.0 x 14mm*
4.1.a.3 Stent 2.0 x 16mm/ *Stent 2.0 x 16mm*
4.1.a.4 Stent 2.0 x 19mm/ *Stent 2.0 x 19mm*
4.1.a.5 Stent 2.0 x 24mm/ *Stent 2.0 x 24mm*

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo II (excepto punto 4) de la Directiva 93/42/CEE

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex II (except Section 4) of Directive 93/42/EEC

Certificado nº/*Certificate no*		Fecha de validez/*Date of validity*			ON nº/*NB no*
2013 07 0801 CT	**Desde/*From***	**31-07-2020**	**Hasta/*To***	**26-05-2024**	**0318**

4.1.a.6 Stent 2.0 x 29mm/ *Stent 2.0 x 29mm*
4.1.a.7 Stent 2.0 x 34mm/ *Stent 2.0 x 34mm*
4.1.a.8 Stent 2.0 x 39mm/ *Stent 2.0 x 39mm*
4.1.a.9 Stent 2.25 x 9mm/ *Stent 2.25 x 9mm*
4.1.a.10 Stent 2.25 x 14mm/ *Stent 2.25 x 14mm*
4.1.a.11 Stent 2.25 x 16mm/ *Stent 2.25 x 16mm*
4.1.a.12 Stent 2.25 x 19mm/ *Stent 2.25 x 19mm*
4.1.a.13 Stent 2.25 x 24mm/ *Stent 2.25 x 24mm*
4.1.a.14 Stent 2.25 x 29mm/ *Stent 2.25 x 29mm*
4.1.a.15 Stent 2.25 x 34mm/ *Stent 2.25 x 34mm*
4.1.a.16 Stent 2.25 x 39mm/ *Stent 2.25 x 39mm*
4.1.a.17 Stent 2.5 x 9mm/ *Stent 2.5 x 9mm*
4.1.a.18 Stent 2.5 x 14mm/ *Stent 2.5 x 14mm*
4.1.a.19 Stent 2.5 x 16mm/ *Stent 2.5 x 16mm*
4.1.a.20 Stent 2.5 x 19mm/ *Stent 2.5 x 19mm*
4.1.a.21 Stent 2.5 x 24mm/ *Stent 2.5 x 24mm*
4.1.a.22 Stent 2.5 x 29mm/ *Stent 2.5 x 29mm*
4.1.a.23 Stent 2.5 x 34mm/ *Stent 2.5 x 34mm*
4.1.a.24 Stent 2.5 x 39mm/ *Stent 2.5 x 39mm*
4.1.a.25 Stent 2.5 x 44mm */ Stent 2,5 x 44mm*
4.1.a.26 Stent 2.5 x 49mm/ *Stent 2,5 x 49mm*
4.1.a.27 Stent 2.75 x 9mm/ *Stent 2.75 x 9mm*
4.1.a.28 Stent 2.75 x 14mm/ *Stent 2.75 x 14mm*
4.1.a.29 Stent 2.75 x 16mm/ *Stent 2.75 x 16mm*
4.1.a.30 Stent 2.75 x 19mm/ *Stent 2.75 x 19mm*
4.1.a.31 Stent 2.75 x 24mm/ *Stent 2.75 x 24mm*
4.1.a.32 Stent 2.75 x 29mm/ *Stent 2.75 x 29mm*
4.1.a.33 Stent 2.75 x 34mm/ *Stent 2.75 x 34mm*
4.1.a.34 Stent 2.75 x 39mm/ *Stent 2.75 x 39mm*
4.1.a.35 Stent 2.75 x 44mm/ *Stent 2,75 x 44mm*
4.1.a.36 Stent 2.75 x 49mm/ *Stent 2,75 x 49mm*
4.1.a.37 Stent 3.0 x 9mm/ *Stent 3.0 x 9mm*

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Certificado nº/*Certificate no*		Fecha de validez/*Date of validity*			ON nº/*NB no*
2013 07 0801 CT	**Desde/*From***	**31-07-2020**	**Hasta/*To***	**26-05-2024**	**0318**

4.1.a.38 Stent 3.0 x 14mm/ *Stent 3.0 x 14mm*
4.1.a.39 Stent 3.0 x 16mm/ *Stent 3.0 x 16mm*
4.1.a.40 Stent 3.0 x 19mm/ *Stent 3.0 x 19mm*
4.1.a.41 Stent 3.0 x 24mm/ *Stent 3.0 x24 mm*
4.1.a.42 Stent 3.0 x 29mm/ *Stent 3.0 x 29mm*
4.1.a.43 Stent 3.0 x 34mm/*Stent 3.0 x 34mm*
4.1.a.44 Stent 3.0 x 39mm/ *Stent 3.0 x 39mm*
4.1.a.45 Stent 3.0 x 44mm/ *Stent 3 mm x 44mm*
4.1.a.46 Stent 3.0 x 49mm/ *Stent 3 mm x 49mm*
4.1.a.47 Stent 3.5 x 9mm/ *Stent 3.50 x 9mm*
4.1.a.48 Stent 3.5 x 14mm/ *Stent 3.5 x 14mm*
4.1.a.49 Stent 3.5 x 16mm/ *Stent 3.5 x 16mm*
4.1.a.50 Stent 3.5 x 19mm/ *Stent 3.5 x 19mm*
4.1.a.51 Stent 3.5 x 24mm/ *Stent 3.5 x 24mm*
4.1.a.52 Stent 3.5 x 29mm/ *Stent 3.5 x 29mm*
4.1.a.53 Stent 3.5 x 34mm/*Stent 3.5 x 34mm*
4.1.a.54 Stent 3.5 x 39mm/ *Stent 3.5 x 39mm*
4.1.a.55 Stent 3.5 x 44mm/ *Stent 3,5 x 44mm*
4.1.a.56 Stent 3.5 x 49mm/*Stent 3.5 x 49mm*
4.1.a.57 Stent 4.0 x 9mm/ *Stent 4.0 x 9mm*
4.1.a.58 Stent 4.0 x 14mm/ *Stent 4.0 x 14mm*
4.1.a.59 Stent 4.0 x 16mm/ *Stent 4.0 x 16mm*
4.1.a.60 Stent 4.0 x 19mm/ *Stent 4.0 x 19mm*
4.1.a.61 Stent 4.0 x 24mm/ *Stent 4.0 x 24mm*
4.1.a.62 Stent 4.0 x 29mm/ *Stent 4.0 x 29mm*
4.1.a.63 Stent 4.0 x 34mm/ *Stent 4.0 x 34mm*
4.1.a.64 Stent 4.0 x 39mm/ *Stent 4.0 x 39mm*
4.1.a.65 Stent 4.0 x 44mm/ *Stent 4.0 mm x 44mm*
4.1.a.66 Stent 4.0 x 49mm/ *Stent 4.0mm x 49mm*
4.1.a.67 Stent 4.5 x 14mm/ *Stent 4.5 x14mm*
4.1.a.68 Stent 4.5 x 16mm/ *Stent 4.5 x 16mm*
4.1.a.69 Stent 4.5 x 19mm/ *Stent 4.5 x 19mm*

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4.1.a.70 Stent 4.5 x 24mm/ *Stent 4.5 x 24mm*
4.1.a.71 Stent 4.5 x 29mm/ *Stent 4.5 x 29mm*
4.1.a.72 Stent 4.5 x 34mm/*Stent4.5 x 34mm*
4.1.a.73 Stent 4.5x39mm/ *Stent 4.5x39mm*

5. Sistema de stent periférico con liberación de sirolimus / *Sirolimus eluting peripheral stent system*

Código NANDO: MD 0201, MDS 7001 y MDS 7006

5.1. Sistema de stent periférico con liberación de sirolimus, con stent de CoCr y polímero bioestable "iVascular angiolite btk*"/"iVascular angiolite btk" Sirolimus eluting peripheral stent system,with CoCr stent and permanent polymer*

Los siguientes productos se encuentran descritos en el certificado 2017 07 0862 ED / *The followed products are described in the certificate 2017 07 0862 ED*

5.1.a. Longitud catéter 142cm/ Catheter length 142cm
5.1.a.1 Stent 2.0 x 9mm/ *Stent 2.0 x 9mm*
5.1.a.2 Stent 2.0 x 14mm/ *Stent 2.0 x14mm*
5.1.a.3 Stent 2.0 x 16mm/ *Stent 2.0 x 16mm*
5.1.a.4 Stent 2.0 x 19mm/ *Stent 2.0 x 19mm*
5.1.a.5 Stent 2.0 x 24mm/ *Stent 2.0 x 24mm*
5.1.a.6 Stent 2.0 x 29mm/ *Stent 2.0 x 29mm*
5.1.a.7 Stent 2.0 x 34mm/ *Stent 2.0 x 34mm*
5.1.a.8 Stent 2.0 x 39mm/ *Stent 2.0 x 39mm*
5.1.a.9 Stent 2.25 x 9mm/ *Stent 2.25 x 9mm*
5.1.a.10 Stent 2.25 x 14mm/ *Stent 2.25 x 14mm*
5.1.a.11 Stent 2.25 x 16mm/ *Stent 2.25 x 16mm*
5.1.a.12 Stent 2.25 x 19mm/ *Stent 2.25 x 19mm*
5.1.a.13 Stent 2.25 x 24mm/ *Stent 2.25 x 24mm*
5.1.a.14 Stent 2.25 x 29mm/ *Stent 2.25 x 29mm*
5.1.a.15 Stent 2.25 x 34mm / *Stent 2.25 x 34mm*

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo II (excepto punto 4) de la Directiva 93/42/CEE

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
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Certificado nº/*Certificate no*		Fecha de validez/*Date of validity*			ON nº/*NB no*
2013 07 0801 CT	**Desde/*From***	**31-07-2020**	**Hasta/*To***	**26-05-2024**	**0318**

5.1.a.16 Stent 2.25 x 39mm/ *Stent 2.25 x 39mm*
5.1.a.17 Stent 2.5 x 9mm/ *Stent 2.5 x 9mm*
5.1.a.18 Stent 2.5 x 14mm/ *Stent 2.5 x 14mm*
5.1.a.19 Stent 2.5 x 16mm/ *Stent 2.5 x 16mm*
5.1.a.20 Stent 2.5 x 19mm/ *Stent 2.5 x 19mm*
5.1.a.21 Stent 2.5 x 24mm/ *Stent 2.5 x 24mm*
5.1.a.22 Stent 2.5 x 29mm/ *Stent 2.5 x 29mm*
5.1.a.23 Stent 2.5 x 34mm/*Stent 2.5 x 34mm*
5.1.a.2 Stent 2.5 x 39mm/ *Stent 2.5 x 39mm*
5.1.a.25 Stent 2.75 x 9mm/ *Stent 2.75 x 9mm*
5.1.a.26 Stent 2.75 x 14mm/ *Stent 2.75x 14mm*
5.1.a.27 Stent 2.75 x 16mm/ *Stent 2.75 x 16mm*
5.1.a.28 Stent 2.75 x 19mm/ *Stent 2.75 x 19mm*
5.1.a.29 Stent 2.75 x 24mm/ *Stent 2.75 x 24mm*
5.1.a.30 Stent 2.75 x 29mm/ *Stent 2.75 x 29mm*
5.1.a.31 Stent 2.75 x 34mm/ *Stent 2.75 x 34mm*
5.1.a.32 Stent 2.75 x 39mm/ *Stent 2.75 x 39mm*
5.1.a.33 Stent 3.0 x 9mm/ *Stent 3.0x9mm*
5.1.a.34 Stent 3.0 x 14mm/ *Stent 3.0 x 14mm*
5.1.a.35 Stent 3.0 x 16mm/ *Stent 3.0 x 16mm*
5.1.a.36 Stent 3.0 x 19mm/ *Stent 3.0 x 19mm*
5.1.a.37 Stent 3.0 x 24mm/ *Stent 3.0 x 24mm*
5.1.a.38 Stent 3.0 x 29mm/ *Stent 3.0 x 29mm*
5.1.a.39 Stent 3.0 x 34mm/ *Stent 3.0 x 34mm*
5.1.a.40 Stent 3.0 x 39mm/ *Stent 3.0 x 39mm*
5.1.a.41 Stent 3.5 x 9mm/ *Stent 3.5 x 9mm*
5.1.a.42 Stent 3.5 x 14mm/ *Stent 3.5 x 14mm*
5.1.a.43 Stent 3.5 x 16mm/ *Stent 3.5 x 16mm*
5.1.a.44 Stent 3.5 x 19mm/ *Stent 3.5 x 19mm*
5.1.a.45 Stent 3.5 x 24mm/ *Stent 3.5 x 24mm*
5.1.a.46 Stent 3.5 x 29mm/ *Stent 3.5 x 29mm*
5.1.a.47 Stent 3.5 x 34mm/ *Stent 3.5 x 34mm*

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Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
2013 07 0801 CT	**Desde/*From***	**31-07-2020**	**Hasta/*To***	**26-05-2024**	**0318**

5.1.a.48 Stent 3.5 x 39mm/ *Stent 3.5 x 39mm*
5.1.a.49 Stent 4.0 x 9mm/ *Stent 4.0 x 9mm*
5.1.a.50 Stent 4.0 x 14mm/ *Stent 4.0 x 14mm*
5.1.a.51 Stent 4.0 x 16mm/ *Stent 4.0 x 16mm*
5.1.a.52 Stent 4.0 x 19mm/ *Stent 4.0 x 19mm*
5.1.a.53 Stent 4.0 x 24mm/ *Stent 4.0 x 24mm*
5.1.a.54 Stent 4.0 x 29mm/ *Stent 4.0 x 29mm*
5.1.a.55 Stent 4.0 x 34mm/ *Stent 4.0 x 34mm*
5.1.a.56 Stent 4.0 x 39mm/ *Stent 4.0 x 39mm*
5.1.a.57 Stent 4.5 x 14mm/ *Stent 4.5 x 14mm*
5.1.a.58 Stent 4.5 x 16mm/ *Stent 4.5 x 16mm*
5.1.a.59 Stent 4.5 x 19mm/ *Stent 4.5 x 19mm*
5.1.a.60 Stent 4.5 x 24mm/ *Stent 4.5 x 24mm*
5.1.a.61 Stent 4.5 x 29mm/ *Stent 4.5 x 29mm*
5.1.a.62 Stent 4.5 x 34mm/ *Stent4.5 x 34mm*
5.1.a.63 Stent 4.5 x 39mm/ *Stent 4.5 x 39mm*

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad.
This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.

Madrid, 29 de julio de 2020
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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ORGANISMO NOTIFICADO 0318

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

CERTIFICADO DE EXAMEN CE DE DISEÑO

de acuerdo con el Anexo II, punto 4, de la Directiva 93/42/CEE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex II, Section 4, of Directive 93/42/EEC
PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: 3-07-2013

Certificado nº/*Certificate No*	**Fecha de validez/*Date of validity***	**ON nº/*NB No***
2013 06 0799 ED	**Desde/*From*: 21-07-2017 Hasta/*To*: 20-07-2022**	**0318**

A favor de /*In favour of:*

Fabricante/*Manufacturer*:
Nombre/*Name:* LIFE VASCULAR DEVICES (LVD) BIOTECH S.L.
Dirección/*Address:* Camí de Can Ubach, 11; Pol. Ind. Les Fallulles
08620 Sant Vicenç Dels Horts- Barcelona
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem
Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category:* Productos de un solo uso / *Single use devices*
Grupo genérico/*Generic group*: Especificados en anexos de este certificado/*Specified in annexes to this certificate*
Tipo/*Type*: Especificados en anexos de este certificado/*Specified in annexes to this certificate.*

Elaborado en/*In the facilities:*

iVascular S.L.U.
Camí de Can Ubach, 11; Pol. Ind. Les Fallulles, 08620 Sant Vicenç Dels Horts- Barcelona

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total nº 2012 07 0788 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate no 2012 07 0788CT*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente nº 2012 01 0327, y garantiza que el diseño del producto descrito cumple los requisitos de la Directiva / *This certificate is issued on the assessment of the design documentation contained in dossier nº 2012 01 0327, and guarantees that the design of the described product fulfils the requirements of the Directive.*

Madrid, 20 de julio de 2017
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de
medicamentos y
productos sanitarios

Fdo. Belén Crespo Sánchez-Eznarriaga

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 20/07/2017
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CORREO ELECTRÓNICO
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ORGANISMO NOTIFICADO 0318

ANEXO Nº/*ANNEX No:*I
CERTIFICADO DE EXAMEN CE DE DISEÑO

de acuerdo con el Anexo II, punto 4, de la Directiva 93/42/CEE
EC DESIGN-EXAMINATION CERTIFICATE

in accordance with Annex II, Section 4, of Directive 93/42/EEC
PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: 3-07-2013

Certificado nº/*Certificate No*	Fecha de validez/*Date of validity*	ON nº/*NB No*
2013 06 0799 ED	**Desde/From: 21-07-2017 Hasta/*To*: 20-07-2022**	**0318**

Producto/ *Device*: Catéter extractor de trombos/ *Thrombus extraction catheter*

Clasificación/*Classification:* III

Catéter extractor de trombos para guía de 0.014" "iVascular capturer"/ *"iVascular capturer" Thrombus extraction catheter.*

Los productos están incluidos en el epígrafe 5.1 del certificado nº 2012 07 0788 CT, y quedan descritos como/ *The products are included in the epigraph 5.1 in the certificate nº 2012 07 0788 CT, and remain described as:*

Longitud de catéter 140cm/ *Catheter length 140cm*

Compatible con catéter guía de 6F/ *6F guide catheter compatible*
Compatible con catéter guía de 7F/ *7F guide catheter compatible*

Accesorios del *producto*/*Product accessories:*

- **Una llave de una vía/** *One stopcock*
- **Una alargadera/** *One extension line*
- **Dos cestos filtrantes/** *Two filter baskets*
- **Dos jeringas de vacío de 30cc con émbolo de bloqueo/***Two 30cc vacuum syringes with locking plunger*

Indicaciones: El catéter extractor de trombos iVascular CAPTURER está especialmente indicado para la extracción de émbolos y trombos blandos de reciente formación en el sistema arterial coronario o periférico, con diámetro mínimo de 2 mm/*The iVascular Capturer thrombus extraction catheter is especially indicated for the removal of fresh, soft emboli and thrombi from the coronary and peripheral vasculature, with a minimum diameter of 2 mm.*

Este certificado ampara todas las marcas del producto incluidas por el fabricante en su declaración de conformidad.
This certificate covers all trademarks of this product included by the manufacturer in his declaration of conformity.

Madrid, 20 de julio de 2017
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Belén Crespo Sánchez-Eznarriaga

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 20/07/2017
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ORGANISMO NOTIFICADO 0318

iVascular®
therapies for living

capturer 6F & 7F

Thrombus extraction catheter

PTFE inner layer

specially designed to minimize friction and assure fast thrombus removal

Innovative tip

guarantees aspiration power in all circumstances

HYDRAX

Durable hydrophilic coating

for sustainable performance and full control

CARDIO

www.ivascular.global

Quick access

Flat-wire braiding
Stiffening mandrel
Hydrophilic coating on the distal part of the device

Increased pushability without kinking to cope with the most tortuous anatomy

Forceful

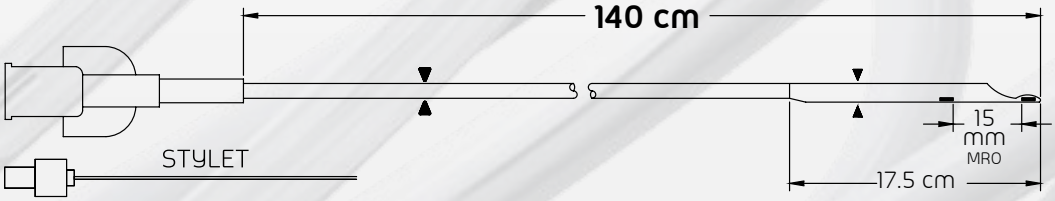
Superior extraction capability:
0.99 mm² (6F) - 1.39 mm² (7F)
PTFE inner layer specially designed to minimize friction and assure fast thrombus removal
Wire mesh through the catheter to avoid collapsing during aspiration

Secure

2 radiopaque markers ensure accurate positioning at all times

Capturer features

- Rapid exchange length: **17.5 cm**
- Usable length: **140 cm**
- Entry profile: **0.021" (6F) - 0.025" (7F)**
- Guiding catheter compatibility **6F & 7F**
- Guidewire compatibility: **0.014"**
- **RO** markers



Product with CE mark, certified by Notified Body 0318

References	
Capturer 6F	DET R14 145 601
Capturer 7F	DET R14 145 701

Distributed by:

INTEGRATED MANUFACTURER

Manufactured by:

Life Vascular Devices Biotech S.L
www.ivascular.global
info@ivascular.global

MP53051 Ed. 1 Feb 2018

TECHNICAL DATA SHEET

angiolite

DESCRIPTION

The sirolimus-eluting coronary stent Angiolite from LVD Biotech SL is made from a cobalt chromium alloy called L605, coated with a mix of sirolimus and biostable polymers. The stent is pre-mounted on the delivery system that will allow implantation on the coronary lesion to treat through the inflation of a balloon at the distal end of the catheter.

The stent is manufactured from a metal tube that is laser cut and subsequently subjected to various treatments that will give the surface a smooth, glossy finish. The stent design is based on a concatenation of cells in the circumferential direction that are connected to each other axially by means of links to obtain different longitudinal configurations. Moreover, the adjustment of the number of cells in the radial direction allows the stent to be expanded to different diameters. The result is an open cell design.

The stent delivery system is a rapid exchange balloon catheter also called RX, having a single lumen configuration on the proximal part and a coaxial double lumen configuration on the distal part. The catheter has an inflatable segment (balloon) in its distal end. The balloon is designed to achieve different diameters and lengths, engaging the stent in its different configurations and covering the range of lesions to be treated. Before positioning, the balloon is folded and the stent is compressed over it. There are radiopaque markers delimiting the length of the stent and to facilitate observation under fluoroscopy. When the balloon reaches the lesion and is inflated, the stent expands against the artery. Subsequently, the balloon is deflated and removed and the stent remains permanently implanted.

The distal part of the catheter is coated with a durable hydrophilic coating to minimize friction and improve its trackability.

TECHNICAL DATA SHEET

angiolite

STENT CHARACTERISTICS	
STENT MATERIAL	CoCr L605
WALL THICKNESS	75 microns for stent 2 to 2.5mm 80 microns for stent 2.75 to 3.5mm 85 microns for stent 4 to 4.5mm
% RECOIL	< 6%
% FORESHORTENING	< 4%
% SURFACE IN CONTACT WITH ARTERY	10-20%
VESSEL CONFORMABILITY	High

DRUG COATING FEATURES	
DRUG	Sirolimus
DRUG DOSE	1,4 µg/mm^2
POLYMER	Biostable

TECHNICAL DATA SHEET

angiolite

CHARACTERISTICS OF THE STENT PRE-MOUNTED ON BALLOON	
MATERIAL	Nylon and Pebax. Final product without latex components
BALLOON	Semi-compliant
NOMINAL PRESSURE	9/10/11 atm
RATED BURST PRESSURE (RBP)	16 atm
AVERAGE BURST PRESSURE (ABP)	22 atm
STENT CROSSING PROFILE (at max. length of the stent)	
Diameter (mm)	INCHES –mm-FRENCH
2.00	0.041 – 1.05 – 3.15
2.25	0.041 – 1.05 – 3.15
2.50	0.041 – 1.05 – 3.15
2.75	0.044 – 1.13 – 3.39
3.00	0.044 – 1.13 – 3.39
3.50	0.045 – 1.15 – 3.45
4.00	0.047 – 1.20 – 3.60
4.50	0.049 – 1.25 – 3.75
RADIOPAQUE MARKERS	
2 metallic markers on the catheter delimiting the stent	
GUIDING CATHETER COMPATIBILITY	5F

TECHNICAL DATA SHEET

angiolite

SYSTEM DIMENSIONS	
Working length of the catheter	142 cm
Catheter shaft (diameter)	2F Proximal 2.6F Middle 2.6F Distal
Distance guidewire entry to tip	25 cm
Entry profile	0.016 inch
Recommended guidewire	0.014 inch
Deflation times	
	< 10 s
Available diameters	2.0 a 4.5 mm
Available lengths	9 a 49 mm

MAXIMUM DIAMETER mm [1]	SMALL	MEDIUM	LARGE
STENT OVEREXPANSION	4.00	5.25	6.00
CELL OF THE SIDE BRANCH ACCESS	3.50	3.75	5.00

[1] These diameters have not been fatigue tested.

TECHNICAL DATA SHEET

angiolite

		STENT DIAMETERS (mm)							
		2.00	2.25	2.50	2.75	3.00	3.50	4.00	4.50
STENT LENGTHS (mm)	9	X	X	X	X	X	X	X	
	14	X	X	X	X	X	X	X	X
	16	X	X	X	X	X	X	X	X
	19	X	X	X	X	X	X	X	X
	24	X	X	X	X	X	X	X	X
	29	X	X	X	X	X	X	X	X
	34	X	X	X	X	X	X	X	X
	39	X	X	X	X	X	X	X	X
	44			X	X	X	X	X	
	49			X	X	X	X	X	

STORAGE & TRANSPORT CONDITIONS

STORAGE: Store in a cool and dry place, away from direct sunlight

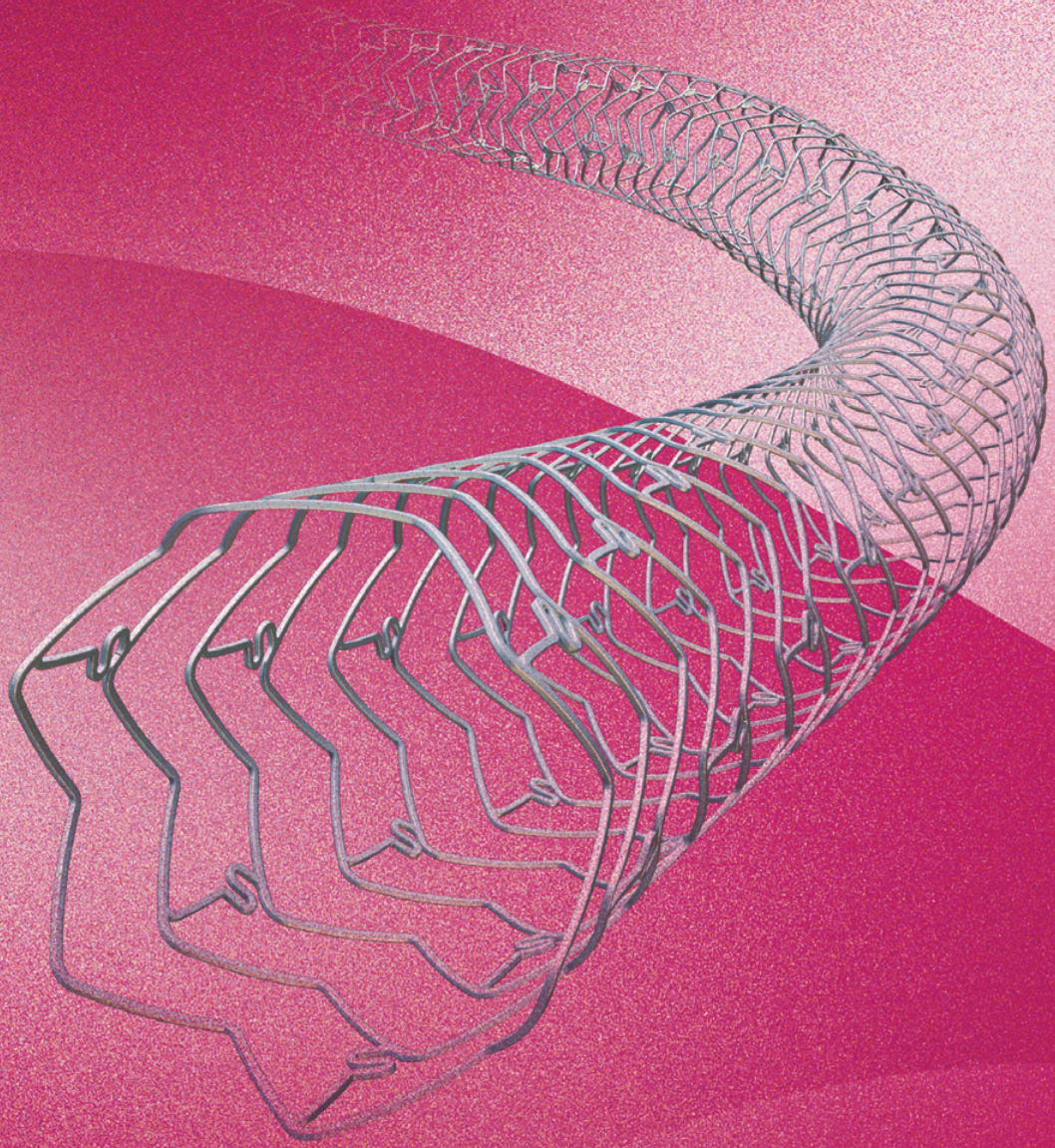
Storage temperature: between **15ºC and 30ºC**

TRANSPORT: During the transport the temperature could reach 40ºC

iVascular®
therapies for living

angiolite

Sirolimus-eluting coronary stent system



The DES we trust

CARDIO

www.ivascular.global

Outstanding safety and efficacy profile

ANCHOR FIM STUDY(1)

Observational, prospective,
multicenter study
103 patients; 2 years follow-up

Angiolite demonstrates favorable early healing properties

Strut coverage at
3 months

86.3%

These outcomes demonstrate Angiolite's excellent performance*

Click here

(1) Puri R, Otaegui I, Sabaté M, et al. *Catheter Cardiovasc Interv. 2017;1–9.*
* Main conclusion of the study

ANGIOLITE RCT(2)

Randomized, non-inferiority, observational, prospective, multicenter trial
223 patients; 2 years follow-up

Angiolite demonstrates non inferiority vs. EES with extraordinary antiproliferative efficacy

LLL at
6 months
0.04mm

Angiolite belongs to the new DES generation**

Click here

(2) Moreu J. et al. EuroIntervention Dec 2019;15:e1081-e1089
**Author conclusion presented at EuroPCR 2018

RANGO REGISTRY(3)

Prospective, single arm, multicenter observational registry
646 patients; 5 years follow-up

Angiolite shows high efficacy and a completely safe profile, even in a high risk population

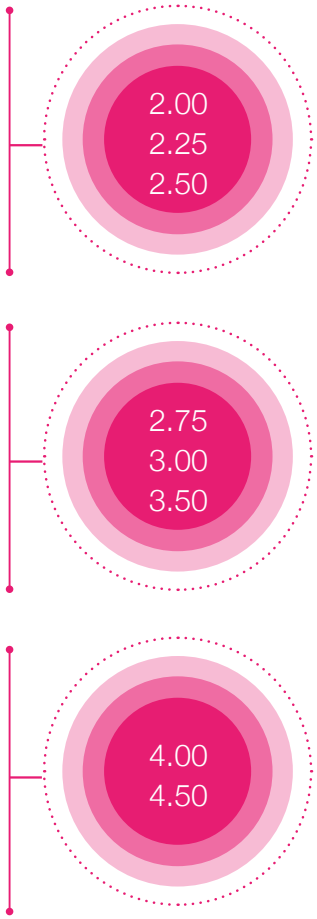
TLF and ST** at
2 years
3.4% and 0.9%

The real-world use of Angiolite warrants the safe use of this potent DES in broader, unselected populations***

(3) RANGO registry accepted in REC Interv Cardiol.
** Stent thrombosis
*** Author conclusion presented at EuroPCR 2021

Excellent performance even in compromised situations

Left main and long bifurcations: Angiolite offers a high overexpansion capacity*



Calcified lesions: Angiolite offers outstanding arterial support

due to an optimal radial force

40%

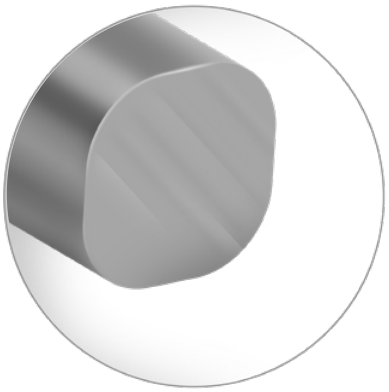
Higher radial force than competitors**

* Angiolite has 3 designs related to stent diameter: S: 2.00 - 2.50mm; M: 2.75 - 3.5mm; L: 4.00 - 4.50mm

** Data on file at iVascular SLU. Average radial force vs Resolute Onyx (Medtronic). Synergy (Boston Scientific) Ultimaster Tansei (Terumo), Orsiro (Biotronik)

Small vessels: Angiolite adapts to the arteries' needs with thin struts

reducing arterial injury and inflammation score(4)**

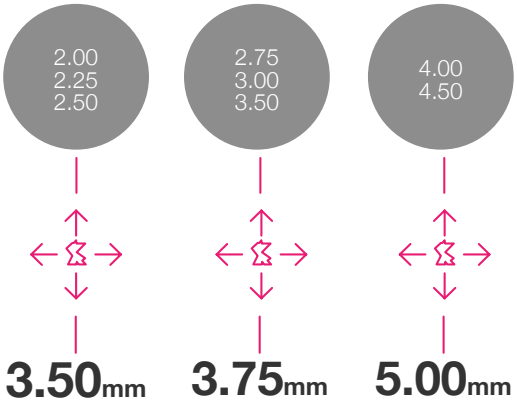


75µm

Bifurcations: Angiolite offers excellent side branch access

Stent diameter

Side branch maximum cell diameter



Diffuse lesions: new long lengths

Angiolite 49mm, one of the longest lengths available on the market

44 and 49mm

** For diameters < 2.75mm

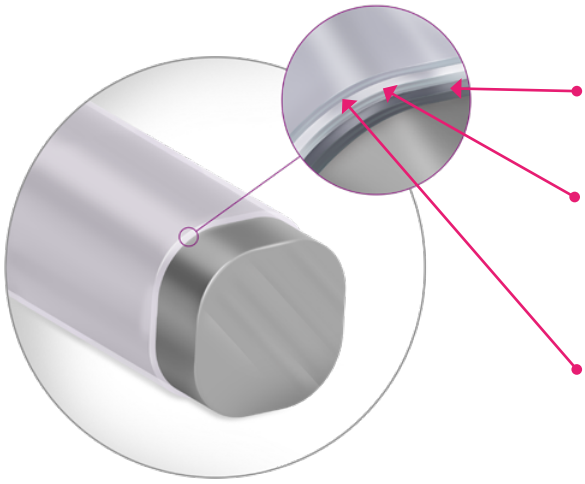
(4) Sripal Bangalore ,et al. Circulation. 2018; 138:2216-2226

High quality of healing

1 Angiolite provides low rates of restenosis and inflammation score[5]

TransferWise
Ensuring homogenous drug elution

TranferWise 3-layer nanotechnology ensures homogenous drug elution



1st layer: Acrylate
Ensures adhesion to the stent

2nd layer: Sirolimus + Fluoro-acrylate polymer
Provides homogenous drug dispersion along the stent

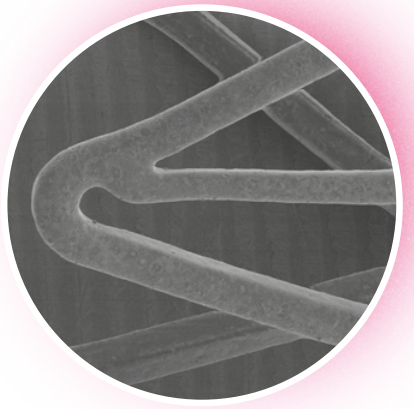
3rd layer: Fluoro-acrylate polymer
Guarantees controlled drug elution

Specific **Design**

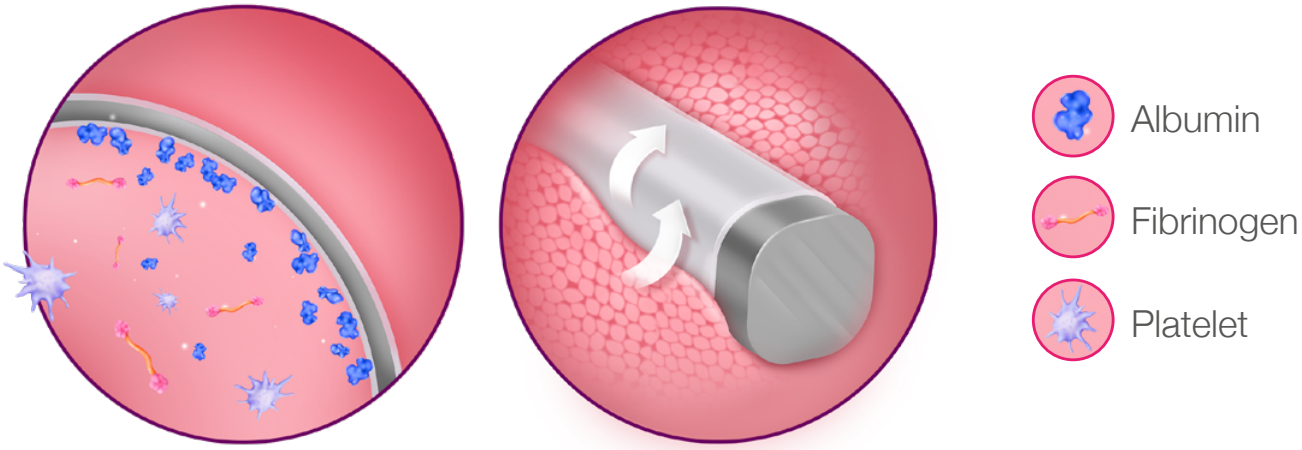
Alternating links ensure homogenouos arterial coverage along the whole stent, which **positively influences the reduction of restenosis and inflammation of the lesion**[5]

(5) Estévez-Loureiro, et al., Rev Esp Cardiol (Engl Ed). 2015;68:1118-24.

2 Angiolite shows low rates of stent thrombosis[1,2,3]



Our fluoro-acrylate polymer provides an early endothelialization and creates a thromboresistant layer. This mechanism suggest to reduce stent thrombosis [6,7,8]



Albumin binds to the fluoro-acrylate polymer, displacing other proteins such as fibrinogen, which is thrombogenic, and creates a tromboresistant layer[7,8,9,10]

(6)In vitro test, data on file iVascular
(7) Ao PY, et al. Eur J Vasc Endovasc Surg. 2000;20:241-249.
(8) Kumaran Kolandaivelu, et al. Circulation. 2011 Apr 5;123(13):1400-9.
(9) Fumiyuki Otsuka, et al. JACC Cardiovasc Interv. 2015 Aug 17;8(9):1248-1260
(10) Otsuka F, et al. Jacc: cardiovascular interventions vol.8, Nº. 9, 2015 Aug 17, 2015: 1248 – 60

Angiolite Features

- Rapid Exchange Catheter (RX)
- Compatible with 0.014” guide wire
- Compatible with 5F guiding catheter
- 2 Radiopaque Makers (Pt - Ir)
- Overexpansion capacity: S: 4.00mm | M: 5.25mm \ L: 6.00mm
- NP: 9-11 atm | RBP: 16 atm | ABP: 22 atm
- Fluoro-acrylate proprietary polymer
- Side Branch access: S: 3.50mm | M: 3.75mm \ L: 5.00mm

Product with CE mark, certified by Notified Body 0318

Stent Diameter (mm)	Effective catheter length 142 cm									
	Stent Length (mm)									
	9	14	16	19	24	29	34	39	44	49
2.00	SCCDSR14150200009	SCCDSR14150200014	SCCDSR14150200016	SCCDSR14150200019	SCCDSR14150200024	SCCDSR14150200029	SCCDSR14150200034	SCCDSR14150200039	-	-
2.25	SCCDSR14150225009	SCCDSR14150225014	SCCDSR14150225016	SCCDSR14150225019	SCCDSR14150225024	SCCDSR14150225029	SCCDSR14150225034	SCCDSR14150225039	-	-
2.50	SCCDSR14150250009	SCCDSR14150250014	SCCDSR14150250016	SCCDSR14150250019	SCCDSR14150250024	SCCDSR14150250029	SCCDSR14150250034	SCCDSR14150250039	SCCDSR14150250044	SCCDSR14150250049
2.75	SCCDSR14150275009	SCCDSR14150275014	SCCDSR14150275016	SCCDSR14150275019	SCCDSR14150275024	SCCDSR14150275029	SCCDSR14150275034	SCCDSR14150275039	SCCDSR14150275044	SCCDSR14150275049
3.00	SCCDSR14150300009	SCCDSR14150300014	SCCDSR14150300016	SCCDSR14150300019	SCCDSR14150300024	SCCDSR14150300029	SCCDSR14150300034	SCCDSR14150300039	SCCDSR14150300044	SCCDSR14150300049
3.50	SCCDSR14150350009	SCCDSR14150350014	SCCDSR14150350016	SCCDSR14150350019	SCCDSR14150350024	SCCDSR14150350029	SCCDSR14150350034	SCCDSR14150350039	SCCDSR14150350044	SCCDSR14150350049
4.00	SCCDSR14150400009	SCCDSR14150400014	SCCDSR14150400016	SCCDSR14150400019	SCCDSR14150400024	SCCDSR14150400029	SCCDSR14150400034	SCCDSR14150400039	SCCDSR14150400044	SCCDSR14150400049
4.50	-	SCCDSR14150450014	SCCDSR14150450016	SCCDSR14150450019	SCCDSR14150450024	SCCDSR14150450029	SCCDSR14150450034	SCCDSR14150450039	-	-

The availability of each reference for the sale is linked to the authorization of commercialization in the country of destination

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info@ ivascular.global

angiolite

Sirolimus-eluting coronary stent system

The DES we trust

MP51111 Ed.8 Jun 2021

DECLARACIÓN CE DE CONFORMIDAD /

EC DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*

LIFE VASCULAR DEVICES BIOTECH, S.L.

Camí de Can Ubach, 11; Pol. Ind. Les Fallulles

08620 Sant Vicenç dels Horts – Barcelona, Spain

DECLARA que los productos incluidos bajo la denominación:

DECLARE that the products included under the name:

SISTEMA DE STENT PERIFÉRICO AUTOEXPANDIBLE

SELF-EXPANDING PERIPHERAL STENT SYSTEM

Marca/*Mark***:** iVascular iVolution pro

que se detallan en documento anexo, están clasificados como productos sanitarios de clase IIb y cumplen con los requisitos esenciales de la Directiva Europea 93/42/CEE, de acuerdo con el Anexo II.

listed in the attached document are classified as class IIb medical devices and comply with the essential requirements requested in the European Directive 93/42/EEC, according to Annex II.

Este documento se emite basándose en la certificación obtenida por el Organismo Notificado nº 0318 (Agencia Española de Medicamentos y Productos Sanitarios): ***Certificado de Sistema de Garantía Total nº 2013 07 0801 CT***

This document is issued on the basis of the certification obtained through the Notified Body No. 0318 (Agencia Española de Medicamentos y Productos Sanitarios): ***EC Full Quality Assurance System Certificate No. 2013 07 0801 CT***

Barcelona, 02 de junio de 2020 (*2nd of June of 2020*)

LIFE VASCULAR DEVICES BIOTECH, S.L.
C.I.F. B-65405169
Cami de Ca n'Ubach, 11
(Pol. Ind. Les Fallulles)
08620 SANT VICENÇ DELS HORTS (Barcelona)

Luis Duocastella Codina

Director General (*CEO*)

LIFE VASCULAR DEVICES BIOTECH, S.L.

SISTEMA DE STENT PERIFÉRICO AUTOEXPANDIBLE
SELF EXPANDING PERIPHERAL STENT SYSTEM

iVascular iVolution pro

DECLARACIÓN CE CONFORMIDAD – ANEXO I: Relación de productos
EC DECLARATION OF CONFORMITY – ANNEX I: List of products

Certificado CE nº/*EC Certificate no.*: 2013 07 0801CT
(Organismo notificado nº/*Notified Body no.* 0318)

1. **Longitud catéter 80cm/***Catheter length: 80cm.*

SPNBC35N080050040	**Stent: Ø 5mm x L 40mm** / *Stent: Ø 5mm x L 40mm*
SPNBC35N080050060	**Stent: Ø 5mm x L 60mm** / *Stent: Ø 5mm x L 60mm*
SPNBC35N080050080	**Stent: Ø 5mm x L 80mm** / *Stent: Ø 5mm x L 80mm*
SPNBC35N080050100	**Stent: Ø 5mm x L 100mm** / *Stent: Ø 5mm x L 100mm*
SPNBC35N080050150	**Stent: Ø 5mm x L 150mm** / *Stent: Ø 5mm x L 150mm*
SPNBC35N080050200	**Stent: Ø 5mm x L 200mm** / *Stent: Ø 5mm x L 200mm*
SPNBC35N080060040	**Stent: Ø 6mm x L 40mm** / *Stent: Ø 6mm x L 40mm*
SPNBC35N080060060	**Stent: Ø 6mm x L 60mm** / *Stent: Ø 6mm x L 60mm*
SPNBC35N080060080	**Stent: Ø 6mm x L 80mm** / *Stent: Ø 6mm x L 80mm*
SPNBC35N080060100	**Stent: Ø 6mm x L 100mm** / *Stent: Ø 6mm x L 100mm*
SPNBC35N080060150	**Stent: Ø 6mm x L 150mm** / *Stent: Ø 6mm x L 150mm*
SPNBC35N080060200	**Stent: Ø 6mm x L 200mm** / *Stent: Ø 6mm x L 200mm*
SPNBC35N080070040	**Stent: Ø 7mm x L 40mm** / *Stent: Ø 7mm x L 40mm*
SPNBC35N080070060	**Stent: Ø 7mm x L 60mm** / *Stent: Ø 7mm x L 60mm*
SPNBC35N080070080	**Stent: Ø 7mm x L 80mm** / *Stent: Ø 7mm x L 80mm*
SPNBC35N080070100	**Stent: Ø 7mm x L 100mm** / *Stent: Ø 7mm x L 100mm*
SPNBC35N080070150	**Stent: Ø 7mm x L 150mm** / *Stent: Ø 7mm x L 150mm*
SPNBC35N080070200	**Stent: Ø 7mm x L 200mm** / *Stent: Ø 7mm x L 200mm*
SPNBC35N080080040	**Stent: Ø 8mm x L 40mm** / *Stent: Ø 8mm x L 40mm*
SPNBC35N080080060	**Stent: Ø 8mm x L 60mm** / *Stent: Ø 8mm x L 60mm*
SPNBC35N080080080	**Stent: Ø 8mm x L 80mm** / *Stent: Ø 8mm x L 80mm*
SPNBC35N080080100	**Stent: Ø 8mm x L 100mm** / *Stent: Ø 8mm x L 100mm*
SPNBC35N080080150	**Stent: Ø 8mm x L 150mm** / *Stent: Ø 8mm x L 150mm*
SPNBC35N080090040	**Stent: Ø 9mm x L 40mm** / *Stent: Ø 9mm x L 40mm*
SPNBC35N080090060	**Stent: Ø 9mm x L 60mm** / *Stent: Ø 9mm x L 60mm*
SPNBC35N080090080	**Stent: Ø 9mm x L 80mm** / *Stent: Ø 9mm x L 80mm*
SPNBC35N080090100	**Stent: Ø 9mm x L 100mm** / *Stent: Ø 9mm x L 100mm*
SPNBC35N080100040	**Stent: Ø 10mm x L 40mm** / *Stent: Ø 10mm x L 40mm*
SPNBC35N080100060	**Stent: Ø 10mm x L 60mm** / *Stent: Ø 10mm x L 60mm*
SPNBC35N080100080	**Stent: Ø 10mm x L 80mm** / *Stent: Ø 10mm x L 80mm*
SPNBC35N080100100	**Stent: Ø 10mm x L 100mm** / *Stent: Ø 10mm x L 100mm*

SISTEMA DE STENT PERIFÉRICO AUTOEXPANDIBLE
SELF EXPANDING PERIPHERAL STENT SYSTEM

iVascular iVolution pro

DECLARACIÓN CE CONFORMIDAD – ANEXO I: Relación de productos
EC DECLARATION OF CONFORMITY – ANNEX I: List of products

Certificado CE nº/*EC Certificate no.*: 2013 07 0801CT
(Organismo notificado nº/*Notified Body no.* 0318)

2. Longitud catéter 130 cm/*Catheter length: 130cm.*

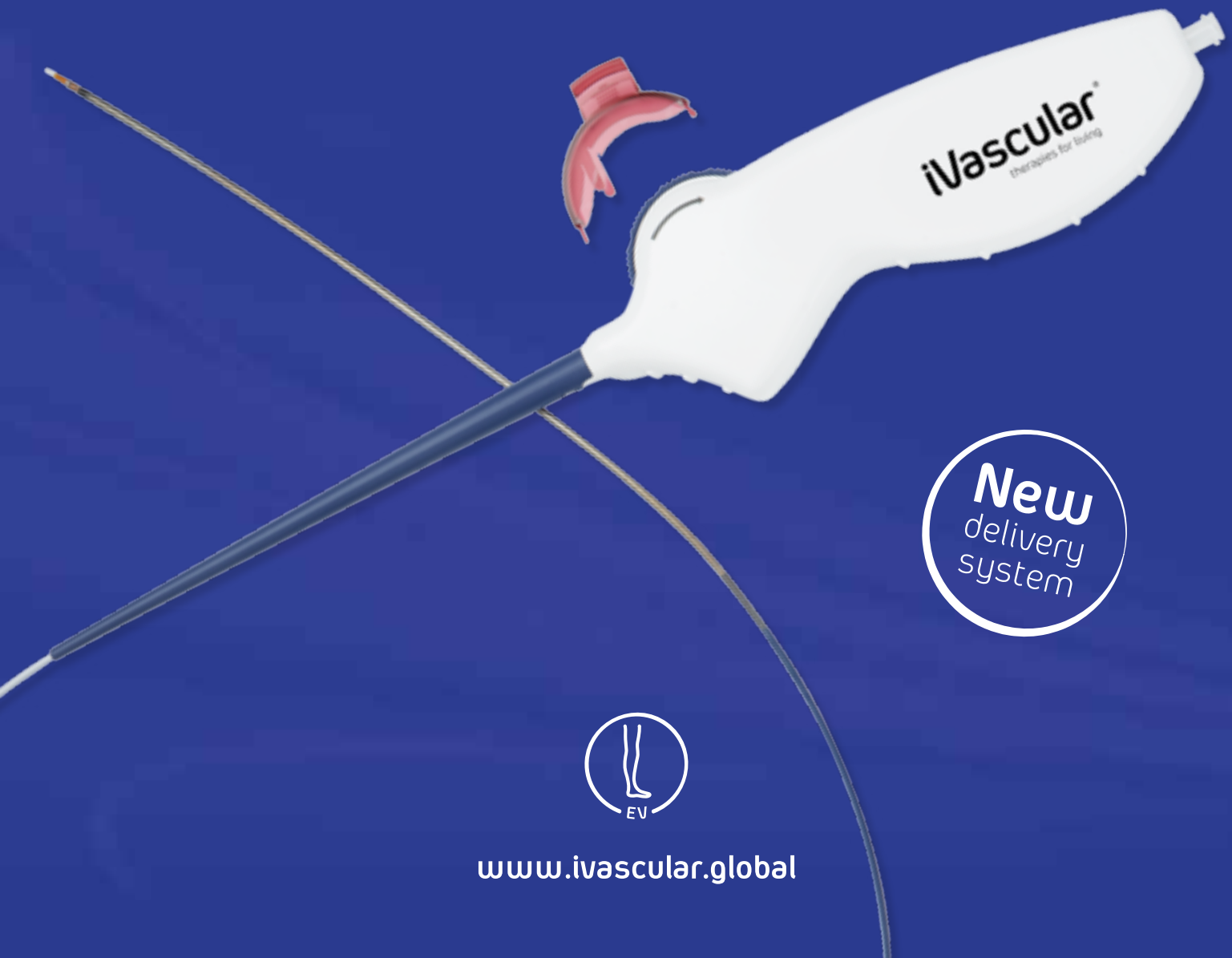
SPNBC35N130050040	**Stent: Ø 5mm x L 40mm** / *Stent: Ø 5mm x L 40mm*
SPNBC35N130050060	**Stent: Ø 5mm x L 60mm** / *Stent: Ø 5mm x L 60mm*
SPNBC35N130050080	**Stent: Ø 5mm x L 80mm** / *Stent: Ø 5mm x L 80mm*
SPNBC35N130050100	**Stent: Ø 5mm x L 100mm** / *Stent: Ø 5mm x L 100mm*
SPNBC35N130050150	**Stent: Ø 5mm x L 150mm** / *Stent: Ø 5mm x L 150mm*
SPNBC35N130050200	**Stent: Ø 5mm x L 200mm** / *Stent: Ø 5mm x L 200mm*
SPNBC35N130060040	**Stent: Ø 6mm x L 40mm** / *Stent: Ø 6mm x L 40mm*
SPNBC35N130060060	**Stent: Ø 6mm x L 60mm** / *Stent: Ø 6mm x L 60mm*
SPNBC35N130060080	**Stent: Ø 6mm x L 80mm** / *Stent: Ø 6mm x L 80mm*
SPNBC35N130060100	**Stent: Ø 6mm x L 100mm** / *Stent: Ø 6mm x L 100mm*
SPNBC35N130060150	**Stent: Ø 6mm x L 150mm** / *Stent: Ø 6mm x L 150mm*
SPNBC35N130060200	**Stent: Ø 6mm x L 200mm** / *Stent: Ø 6mm x L 200mm*
SPNBC35N130070040	**Stent: Ø 7mm x L 40mm** / *Stent: Ø 7mm x L 40mm*
SPNBC35N130070060	**Stent: Ø 7mm x L 60mm** / *Stent: Ø 7mm x L 60mm*
SPNBC35N130070080	**Stent: Ø 7mm x L 80mm** / *Stent: Ø 7mm x L 80mm*
SPNBC35N130070100	**Stent: Ø 7mm x L 100mm** / *Stent: Ø 7mm x L 100mm*
SPNBC35N130070150	**Stent: Ø 7mm x L 150mm** / *Stent: Ø 7mm x L 150mm*
SPNBC35N130070200	**Stent: Ø 7mm x L 200mm** / *Stent: Ø 7mm x L 200mm*
SPNBC35N130080040	**Stent: Ø 8mm x L 40mm** / *Stent: Ø 8mm x L 40mm*
SPNBC35N130080060	**Stent: Ø 8mm x L 60mm** / *Stent: Ø 8mm x L 60mm*
SPNBC35N130080080	**Stent: Ø 8mm x L 80mm** / *Stent: Ø 8mm x L 80mm*
SPNBC35N130080100	**Stent: Ø 8mm x L 100mm** / *Stent: Ø 8mm x L 100mm*
SPNBC35N130080150	**Stent: Ø 8mm x L 150mm** / *Stent: Ø 8mm x L 150mm*
SPNBC35N130090040	**Stent: Ø 9mm x L 40mm** / *Stent: Ø 9mm x L 40mm*
SPNBC35N130090060	**Stent: Ø 9mm x L 60mm** / *Stent: Ø 9mm x L 60mm*
SPNBC35N130090080	**Stent: Ø 9mm x L 80mm** / *Stent: Ø 9mm x L 80mm*
SPNBC35N130090100	**Stent: Ø 9mm x L 100mm** / *Stent: Ø 9mm x L 100mm*
SPNBC35N130100040	**Stent: Ø 10mm x L 40mm** / *Stent: Ø 10mm x L 40mm*
SPNBC35N130100060	**Stent: Ø 10mm x L 60mm** / *Stent: Ø 10mm x L 60mm*
SPNBC35N130100080	**Stent: Ø 10mm x L 80mm** / *Stent: Ø 10mm x L 80mm*
SPNBC35N130100100	**Stent: Ø 10mm x L 100mm** / *Stent: Ø 10mm x L 100mm*

iVascular®
therapies for living

iVolution pro

Self-expanding peripheral stent system

Quality as first option



New delivery system

EV

www.ivascular.global

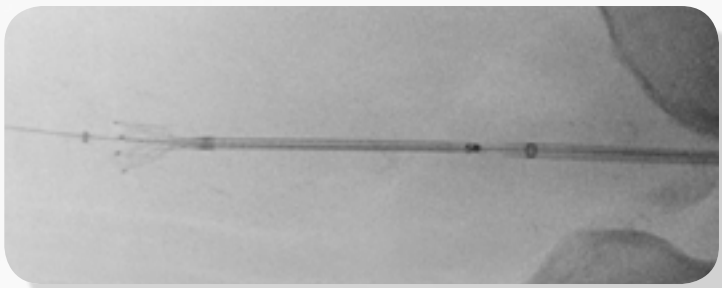
New delive

Simple and controlled stent deployment

No jumping effect

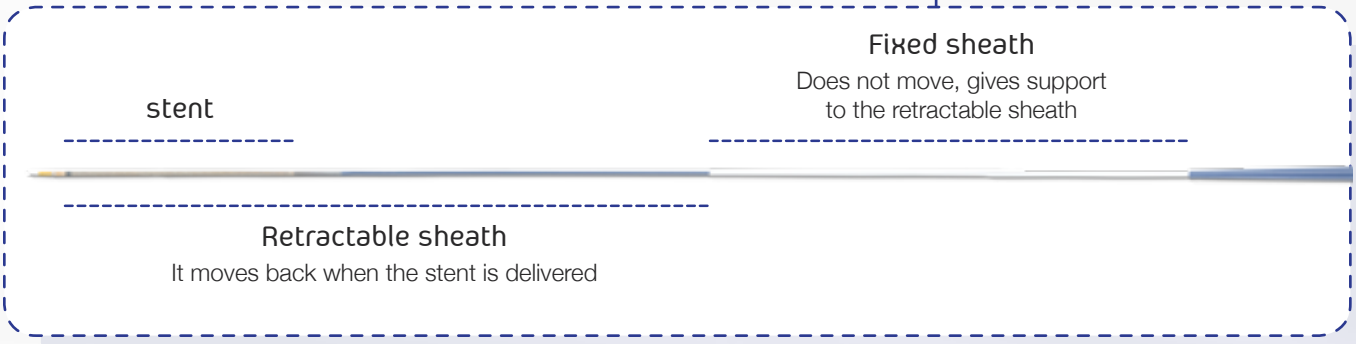
Optimum visibility

- 2 markers delimiting the stent
- 1 tungsten marker in the retractable sheath indicating the implantation level



Triple sheath design

to control deployment forces and facilitate precise placement

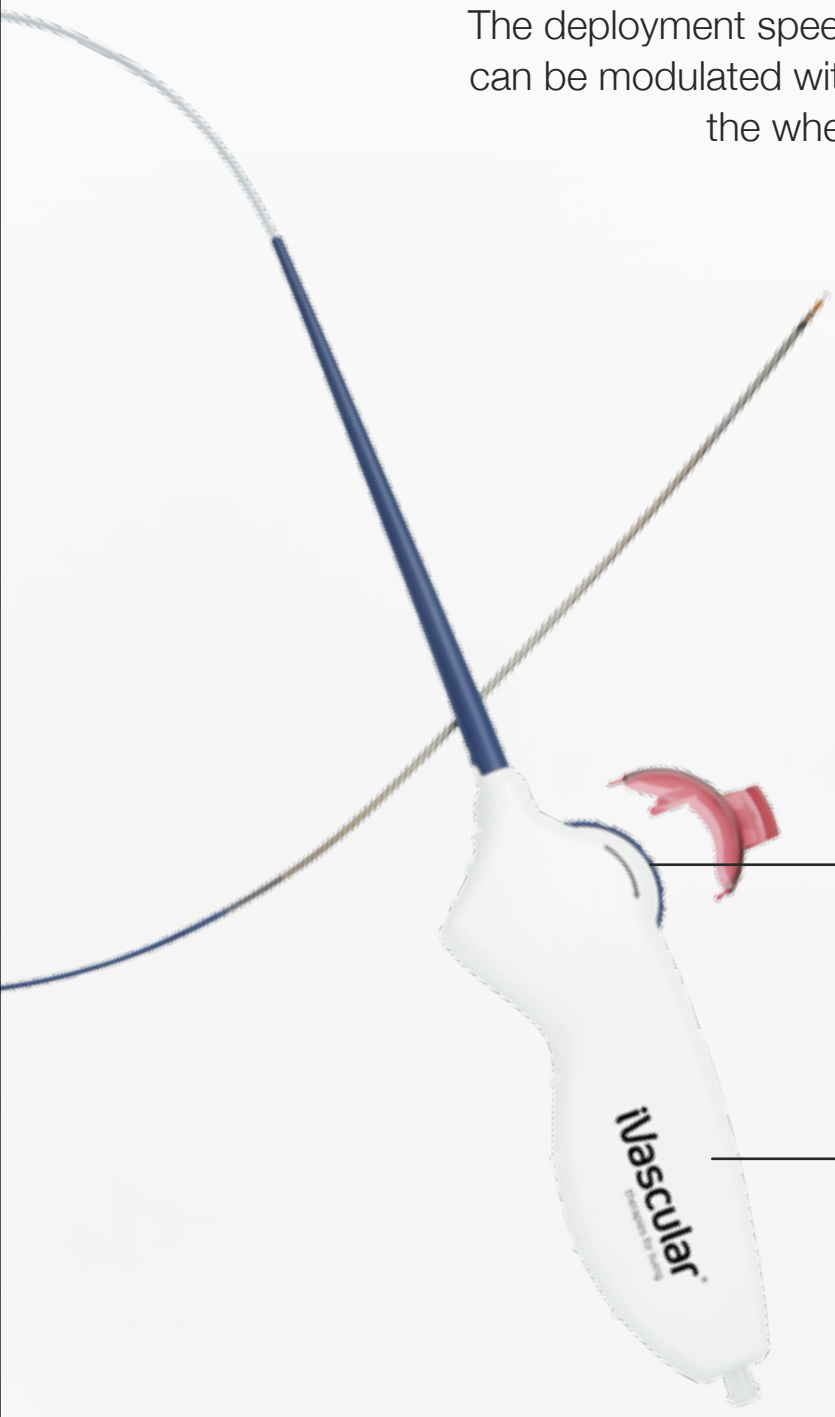


*iVascular internal data

ery system

Controlled deployment

The deployment speed can be modulated with the wheel



Ergonomic and small handle

10cm shorter than main competitors*

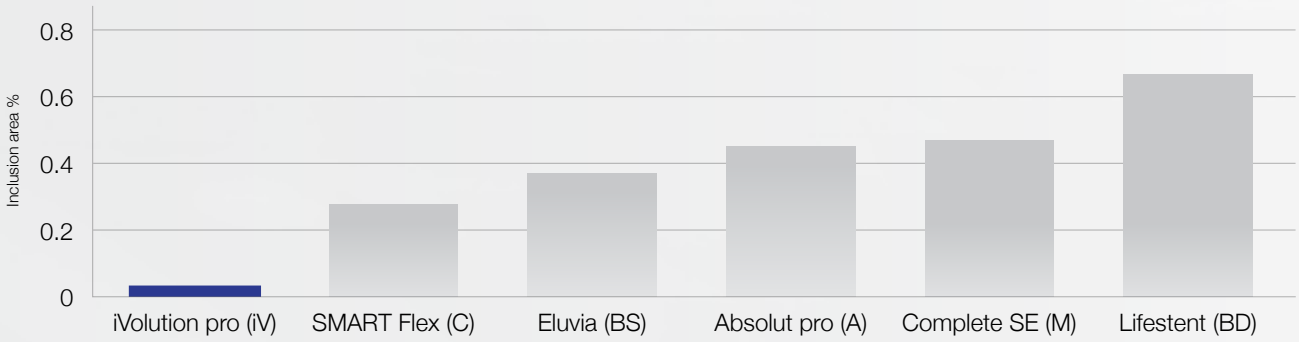
Stent quality

Quality assured to avoid stent fracture

100% of stents checked

No reported stent fractures in the EVOLUTION trial at 1-year[1]

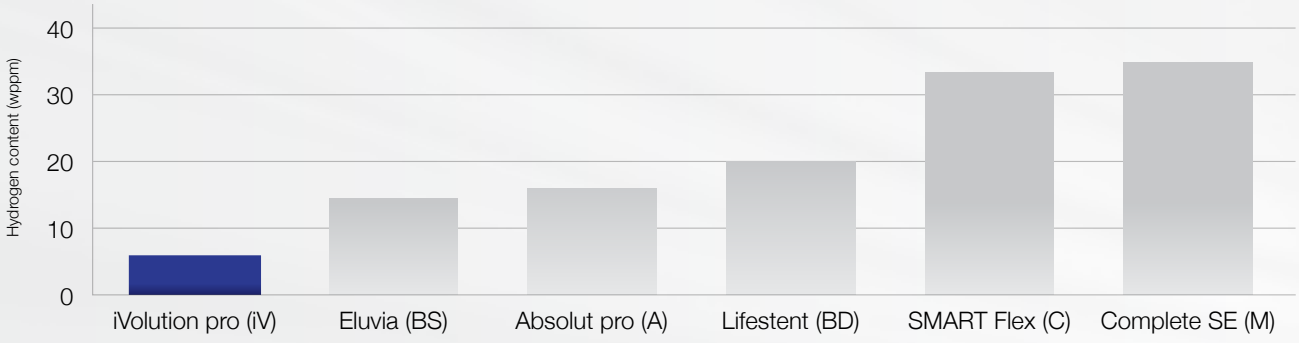
Best corrosion resistance and **lowest inclusion fraction** reported[2]



Inclusions are small particles inside the nitinol matrix. They are known as a fatigue starting points

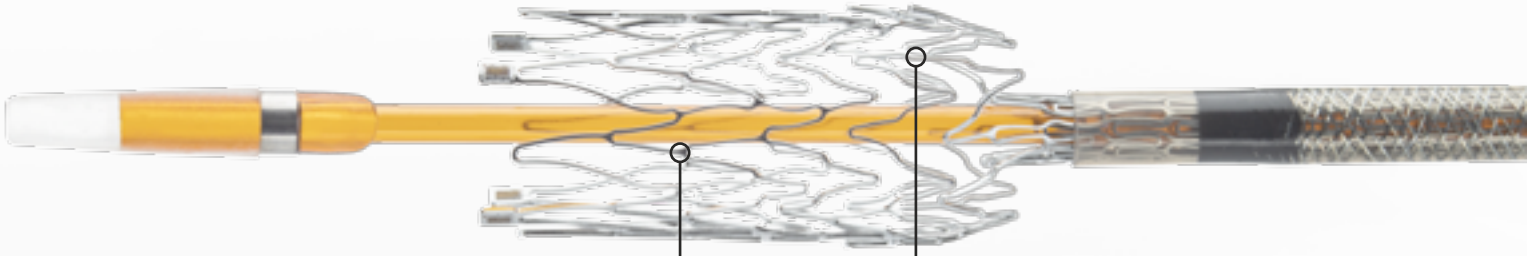
Highest elastic recovery & **minimum brittleness**

Hydrogen in stent can suppress elastic recovery and promote brittleness. iVolution pro is the stent with lowest hydrogen content[3]



[1] M Bosiers et al. EVOLUTION Study: 12-month results. 2019 Aug;60(4):490-495.
[2] F Sun et al. On the High Sensitivity of Corrosion Resistance of NiTi Stents with Respect to Inclusions: An Experimental Evidence, ACS Omega, 2020
[3] F Sun et al. Revisiting the effects of low-concentration hydrogen in NiTi self-expandable stents. Materials Science & Engineering C 118 (2021) 111405

Stent design



Resistance

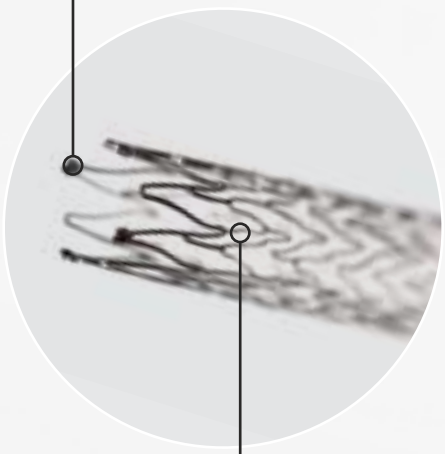
Stress homogeneously distributed to avoid stent fracture

Flexibility

Open cell design to offer the highest flexibility

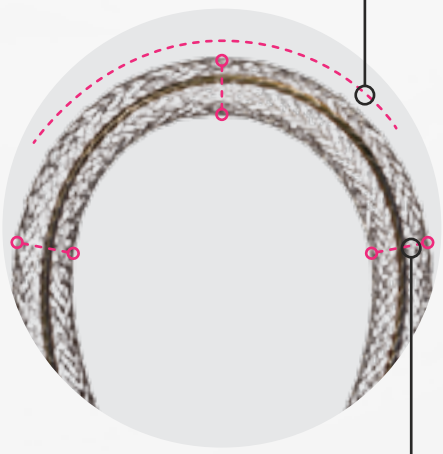
Visibility

4 tantalum markers at each end



No flaking

Avoids vessel wall damage



No jumping effect

Closed cell design ends for deployment stability

Anti-kinking

Maintains inner lumen

Clinical e

Highest efficacy outcomes

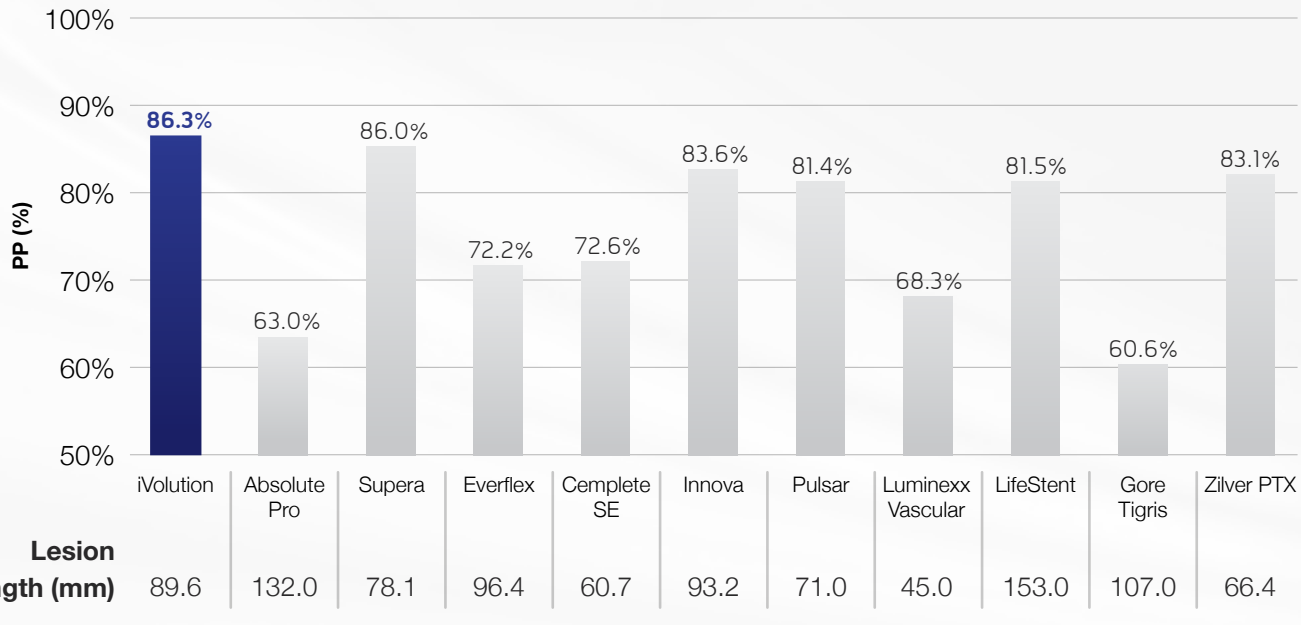
EVOLUTION Trial[1]

- Physician-initiated, prospective, and multicentric trial, investigating the efficacy of iVolution
- PI: Dr Marc Bosiers
- N:120 patients
- Symptomatic (Rutherford 2-4) femoropopliteal arterial stenotic or occlusive lesions.
- Follow-up: 1 year

PP
86.3%

fTLR
88.0%

Primary patency comparison



evidence

in femoropopliteal arteries

TINTIN Trial (1-year follow-up)[2]

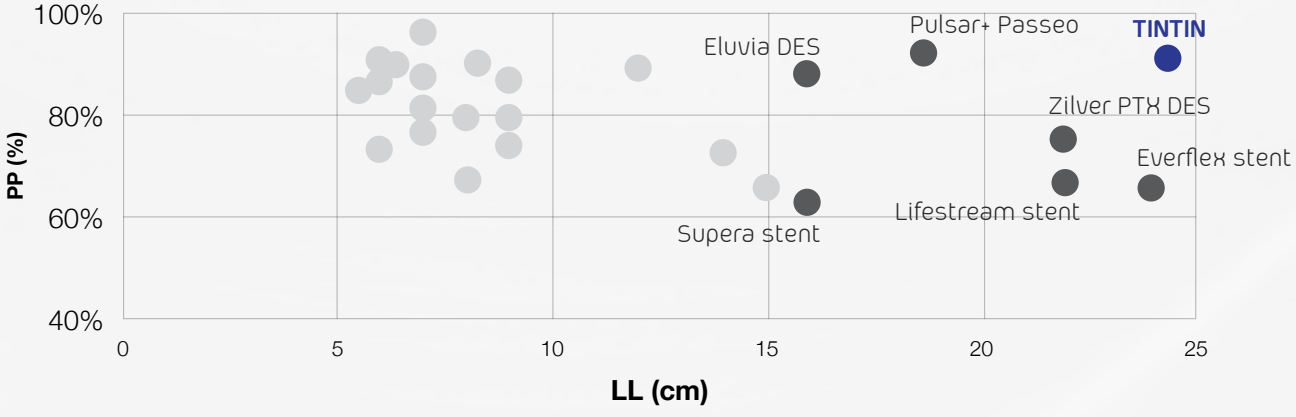
- Physician initiated, prospective, multi-center trial, investigating the safety and efficacy of the treatment with Luminor and iVolution
- PI: Dr Koen Deloose
- N: 100 patients
- TASC C and D femoropopliteal atherosclerotic lesions
- Follow-up: 1, 2, 3, 4 and 5 years

Main lesion length
24.3cm

fTLR
94.4%

PP
90.5%

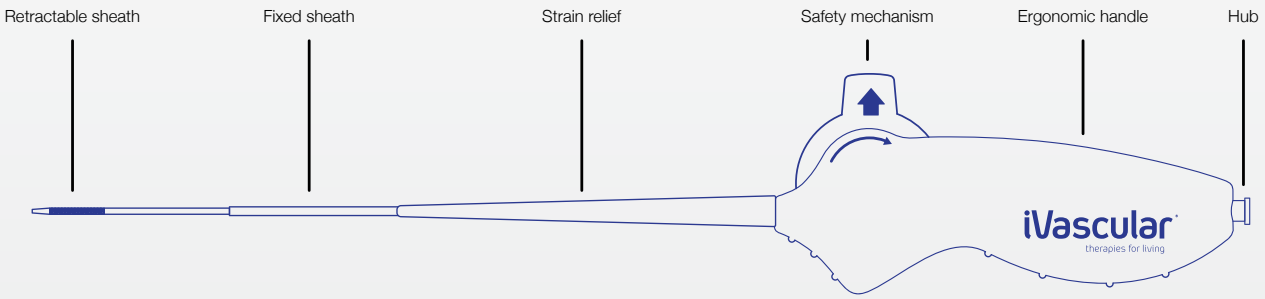
Comparison of main lesion length vs PP at 1-year follow up between 26 trials



[1] M Bosiers et al. EVOLUTION Study: 12-month results. 2019 Aug;60(4):490-495. [2] K Deloose. LINC 2020 presentation

iVolution pro
features

- **Triple sheath** catheter
- Catheter length: **80** and **130** cm
- Introducer compatibility: **6F**
- Guiding catheter compatibility: **8F**
- Portfolio:
  - Ø: 5-10mm
  - Length: 40-200mm
- Guidewire compatibility: **0.035”**



Product with CE mark, certified by Notified Body 0318

Usable catheter length (cm)	Stent Diameter (mm)	Stent length (mm)					
		40	60	80	100	150	200
80	5	SPNBC35N080050040	SPNBC35N080050060	SPNBC35N080050080	SPNBC35N080050100	SPNBC35N080050150	SPNBC35N080050200
	6	SPNBC35N080060040	SPNBC35N080060060	SPNBC35N080060080	SPNBC35N080060100	SPNBC35N080060150	SPNBC35N080060200
	7	SPNBC35N080070040	SPNBC35N080070060	SPNBC35N080070080	SPNBC35N080070100	SPNBC35N080070150	SPNBC35N080070200
	8	SPNBC35N080080040	SPNBC35N080080060	SPNBC35N080080080	SPNBC35N080080100	SPNBC35N080080150	-
	9	SPNBC35N080090040	SPNBC35N080090060	SPNBC35N080090080	SPNBC35N080090100	-	-
	10	SPNBC35N080100040	SPNBC35N080100060	SPNBC35N080100080	SPNBC35N080100100	-	-
130	5	SPNBC35N130050040	SPNBC35N130050060	SPNBC35N130050080	SPNBC35N130050100	SPNBC35N130050150	SPNBC35N130050200
	6	SPNBC35N130060040	SPNBC35N130060060	SPNBC35N130060080	SPNBC35N130060100	SPNBC35N130060150	SPNBC35N130060200
	7	SPNBC35N130070040	SPNBC35N130070060	SPNBC35N130070080	SPNBC35N130070100	SPNBC35N130070150	SPNBC35N130070200
	8	SPNBC35N130080040	SPNBC35N130080060	SPNBC35N130080080	SPNBC35N130080100	SPNBC35N130080150	-
	9	SPNBC35N130090040	SPNBC35N130090060	SPNBC35N130090080	SPNBC35N130090100	-	-
	10	SPNBC35N130100040	SPNBC35N130100060	SPNBC35N130100080	SPNBC35N130100100	-	-

The availability of each reference for the sale is linked to the authorization of commercialization in the country of destination

Introducer compatibility: **6F**

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