Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 95054
Tel 408-845-3000
Fax 408-845-3333

DECLARATION OF CONFORMITY

Manufacturer:	Abbott Vascular
Address:	3200 Lakeside Drive Santa Clara, California 95054, USA
Manufacturing Location:	Abbott Vascular 52 Calle 3, B31 Coyol Free Zone El Coyol Alajuela, Costa Rica
Device Name:	**Armada 35 & Armada 35 LL PTA Catheter**
Device Classification:	Class IIa
GMDN Code:	17184 Peripheral angioplasty balloon catheter, basic
Classification Rationale:	The following Annex IX definition(s) apply to the **Armada 35 & Armada 35 LL PTA Catheter** for purposes of classifications: Per Rule 6, Annex IX, all surgically invasive devices intended for transient use are in Class IIa unless they are: Intended specifically to control, diagnose, monitor, or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III.
Authorized European Representative:	Abbott Vascular International BVBA Park Lane, Culliganlaan 2B 1831 Diegem, Belgium

Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 95054
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Model Numbers: **Armada 35 & Armada 35 LL PTA Catheter**

Balloon length / Balloon diameter, shaft length	20mm	40mm	60mm	80mm	100mm	120mm	150mm	200mm	250mm
3.0mm, 80cm	B1030-020	B1030-040	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
4.0mm, 80cm	B1040-020	B1040-040	B1040-060	B1040-080	B1040-100	B1040-120	B1040-150	B1040-200	B1040-250
5.0mm, 80cm	B1050-020	B1050-040	B1050-060	B1050-080	B1050-100	B1050-120	B1050-150	B1050-200	B1050-250
6.0mm, 80cm	B1060-020	B1060-040	B1060-060	B1060-080	B1060-100	B1060-120	B1060-150	B1060-200	B1060-250
7.0mm, 80cm	B1070-020	B1070-040	B1070-060	B1070-080	B1070-100	B1070-120	B1070-150	B1070-200	n.a.
8.0mm, 80cm	B1080-020	B1080-040	B1080-060	B1080-080	n.a.	n.a.	n.a.	n.a.	n.a.
9.0mm, 80cm	B1090-020	B1090-040	B1090-060	B1090-080	n.a.	n.a.	n.a.	n.a.	n.a.
10.0mm, 80cm	B1100-020	B1100-040	B1100-060	B1100-080	n.a.	n.a.	n.a.	n.a.	n.a.
12.0mm, 80cm	B1120-020	B1120-040	B1120-060	B1120-080	n.a.	n.a.	n.a.	n.a.	n.a.
14.0mm, 80cm	B1140-020	B1140-040	B1140-060	B1140-080	n.a.	n.a.	n.a.	n.a.	n.a.
3.0mm, 135cm	B2030-020	B2030-040	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
4.0mm, 135cm	B2040-020	B2040-040	B2040-060	B2040-080	B2040-100	B2040-120	B2040-150	B2040-200	B2040-250
5.0mm, 135cm	B2050-020	B2050-040	B2050-060	B2050-080	B2050-100	B2050-120	B2050-150	B2050-200	B2050-250
6.0mm, 135cm	B2060-020	B2060-040	B2060-060	B2060-080	B2060-100	B2060-120	B2060-150	B2060-200	B2060-250
7.0mm, 135cm	B2070-020	B2070-040	B2070-060	B2070-080	B2070-100	B2070-120	B2070-150	B2070-200	n.a.
8.0mm, 135cm	B2080-020	B2080-040	B2080-060	B2080-080	n.a.	n.a.	n.a.	n.a.	n.a.
9.0mm, 135cm	B2090-020	B2090-040	B2090-060	B2090-080	n.a.	n.a.	n.a.	n.a.	n.a.
10.0mm, 135cm	B2100-020	B2100-040	B2100-060	B2100-080	n.a.	n.a.	n.a.	n.a.	n.a.
12.0mm, 135cm	B2120-020	B2120-040	B2120-060	B2120-080	n.a.	n.a.	n.a.	n.a.	n.a.
14.0mm, 135cm	B2140-020	B2140-040	B2140-060	B2140-080	n.a.	n.a.	n.a.	n.a.	n.a.

I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I and Annex II (except part 4) of EC Council Directive 93/42/EEC.

Directive 2006/42/EC on Machinery and directive 89/686/EEC on Personal Protective Equipment do not apply.

This declaration is supported by an EC quality system listed below.

Supporting Certificates:

EC Quality Management System, ISO 13485:2003 Certificate Number: FM 72377
Annex II Certificate Number: CE 510108

Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 95054
Tel 408-845-3000
Fax 408-845-3333

Notified Body: British Standards Institution, a notified body authorized by the United Kingdom Competent Authority, Notified Body Identification Number 0086.

British Standards Institution
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MK5 8PP
United Kingdom

This Declaration of Conformity is valid until its revision, or with the obsolescence of the supporting Annex II certificate listed above.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Authorized Signatory: N Manthani Date: 11-May-2017

Namratha Manthani
Sr. Regulatory Affairs Specialist
Abbott Vascular

Issued by: _____ Date: 15-MAY-2017

Steven Eldridge
Divisional VP, AV Global Quality and Compliance
Abbott Vascular

Place of issue: Temecula Date of issue: 15-MAY-2017

Effective Date: 15-MAY-2017

CERTIFICATE

EC Certificate No. 1434-MDD-389/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Meril Life Sciences Pvt. Ltd.

Muktanand Marg, Chala, Vapi-396191, Gujarat, India

for the design, manufacture and final inspection of

medical devices, class III

BioMime™ Sirolimus Eluting Coronary stent system

List of medical devices covered by this certificate is given in the Annex no. 1, 2, 3 , 4, 5 to the EC Design-examination Certificate No. 1434-MDD-390/2019

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 26.07.2019 to 13.11.2022

The date of issue of the Certificate: 26.07.2019

CE 1434

Mgr Anna Wyroba
Vice-President

Application No: 214/2019
Module H

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

Certificate No. **1434-MDD-389/2019**
Issued under the Contract No. **MD-131/2019**
Bears the PCBC hologram
Warsaw, 26/07/2019

DECLARATION OF CONFORMITY

Manufacturer's Name:	**MERIL LIFE SCIENCES PVT. LTD.**
Manufacturer's Address:	Muktanand Marg, Chala, Vapi - 396191 Gujarat, India.
Product Name:	**BioMime™ - Sirolimus Eluting Coronary Stent System**
Product Details:	GMDN Code P 58771 Control No.: DOC/BIO/Rev.08/04.12.2015 Batch No.: _____ Mfg. Date: _____ Batch Size: _____ Expiry Date: _____ Conforms to the applicable national/ international Standards.

1. We declare that our products as listed below, comply to the requirements to Medical device Directive 93/42/EEC as amended by directive 2007/47/EC.
   A. **BioMime™ –Sirolimus Eluting Coronary Stent System.**
2. Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per EN ISO 13485:2012/ISO 13485:2003 & ISO 9001:2008.
3. Company authorizes the notified body to carry out necessary inspection and agrees to supply the required information & data/documents from time to time.
4. Company agrees to make available all relevant Documents & Data of the products to the National and competent Authority for a period ending 15 (Fifteen) years after the last product has been manufactured.
5. Company or his authorized representative shall fulfill the obligations imposed by Annex II (Full Quality Assurance system) of Medical Device Directive 93/42/EEC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
6. Company undertakes to keep up to date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.
7. Company undertakes to notify immediately any malfunction /deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market.
8. Company shall fulfill the obligations imposed by Annex I of Medical Device Directive 93/42/EEC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.

List of Standard Applied:	MDD/93/42/EEC as amended by Directive 2007/47/EC, DIRECTIVE 65/65/EEC, EN ISO 13485:2012, ISO 13485-2003, ISO 9001: 2008, EN ISO 14971:2012, ISO 15223-1:2012, EN 1041:2008 A1:2013, EN ISO 25539-2:2012, EN ISO10993-1:2009, EN ISO 11135-1:2014, EN ISO 11607-1:2009, ASTM F 1980-07.
Conformity Assessment Route:	Annex: II. of MDD/93/42/EEC on Medical Devices as amended.
Device Classification:	As per MDD/93/42/EEC, 14th June 1993, Annexure IX, Rule 13, i.e. BioMime™ – Sirolimus Eluting Coronary Stent System incorporates, as an integral part, a subsatance which, if used seperatly can be considered to be a Medicinal Product, as defined in Article 1 of Directive 65/65/EEC, Hence it is classified as class III Medical Device. The product is CE marked (CE certificate No. 10 0968 QS/NB/d and 12 0414 QS/NB/b, EC Design Examination Certificate No. 10 0969 CN/NB/e and 12 0415 CN/NB/c valid until 29 November 2017, Notified Body No. 1023).
European Authorized Representative:	Obelis s.a., Bd. General Wahis 53, 1030 Brussels, Belgium. Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Notifying Body:	INSTITUTE FOR TESTING AND CERTIFICATION, a.s., trida Tomase Bati 299, Louky, 763 02 Zlin, Czech Republic – www.itczlin.cz (NB 1023)
Signature:	
Name:	Mr. Narendra Patel
Designation:	Head – QA
Date/Location:	**Date:** 04/12/2015 **Location:** Vapi, Gujarat, INDIA

MERIL LIFE SCIENCES (P) LTD. VAPI

CE 1023

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. I1 16 09 10275 394

Manufacturer:

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin
GERMANY

Product:

Active Implants
(see attachment)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. See also notes overleaf.

Report No.: 713080958

Valid from: 2016-10-26
Valid until: 2021-10-25

Date, 2016-08-18

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. I1 16 09 10275 394

Facility(ies):

BIOTRONIK SE & Co. KG
Woermannkehre 1, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Ballinstrasse 20, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Ballinstrasse 16-18, 12359 Berlin, GERMANY

Design Facility(ies):

BIOTRONIK SE & Co. KG
Woermannkehre 1, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Woermannkehre 2, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Buschkrugallee 21a, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Buschkrugallee 21b, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Sieversufer 7-9, 12359 Berlin, GERMANY

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Product Service

Attachment for Certificate no I1 16 09 10275 394
dated 2016-10-26

Products / Product Categories:

I. ANTIBRADYCARDIA DEVICES

1. Implantable pacemakers incl. accessories
2. Implantable leads with / without drug component incl. accessories
3. Programmers and measuring devices for implantable pacemakers
4. External threshold analyzer
5. External monitors for pacemaker

II. ANTITACHYCARDIA DEVICES

1. Implantable cardioverter / defibrillators incl. accessories
2. Implantable leads with / without drug component incl. accessories
3. Devices for the intraoperative application and follow-up incl. accessories
4. Programmers and measuring devices for implantable cardioverter / defibrillators incl. accessories

III. MEDICAL TELEMONITORING SYSTEMS

1. Active implantable devices incl. accessories
2. Receivers and transmitters incl. accessories
3. Service center incl. accessories

IV. ACTIVE IMPLANTABLE DIAGNOSTIC DEVICES

1. Implantable cardiac monitoring and recording systems

Munich, CRT2, 2016-08-18

Stefan Preiß
Certification Medical Technology

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

Beglaubigte Abschrift

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 010275 0511 Rev. 01

Holder of Certificate: **BIOTRONIK SE & Co. KG**
Woermannkehre 1
12359 Berlin
GERMANY

Certification Mark:

Scope of Certificate: Design, development, manufacture and distribution of implantable pacemaker systems, implantable cardioverter/defibrillator systems, implantable cardiac monitoring and recording systems, programmers for cardiac implantable devices, application software (external), leads for Brady IPGs, leads for Tachy IPGs, leads for heart failure treatment, lead implantation systems, pacing system analyzers, external pacemakers, stimulators for electrophysiological applications, generators and analyzers for high frequency ablation, telemonitoring systems, patient cables, adaptors, lead extensions and lead caps;
Servicing of telemonitoring systems, programmers for cardiac implantable devices, pacing system analyzers, external pacemakers, stimulators for electrophysiological applications and generators and analyzers for high frequency ablation

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713165065

Valid from: 2020-07-01
Valid until: 2023-06-30

Date, 2020-04-23

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performe

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (e princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o dir ao uso da marca de certificação e para certific de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 010275 0511 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

BIOTRONIK SE & Co. KG
Woermannkehre 1, 12359 Berlin, GERMANY

BIOTRONIK Corporate Services SE
Sieversufer 7-9, 12359 Berlin, GERMANY

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
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- Regular surveillance of the facility is performe

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维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

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認証書の有効性に関する原則的な要求事項
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Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direit ao uso da marca de certificação e para certificad de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

I hereby certify that the above copy is a true copy of the original document which has been presented to me.

Berlin, June, 18 2020

Notary

9101a E-F

Apostille
(Convention de La Haye du 5 octobre 1961)

1. Land: Bundesrepublik Deutschland
   Diese öffentliche Urkunde
2. ist unterschrieben von Daniel C r e u t z b u r g
3. in seiner Eigenschaft als Notar in Berlin
4. sie ist versehen mit dem Siegel
   des Notars

Bestätigt

5. in Berlin 6. am 23. Juni 2020
7. durch den Präsidenten des Landgerichts in Berlin
8. unter Nr. 9101a E-F 4835/20
9. Siegel

10. Unterschrift
Im Auftrag

(R u n g e)
Vorsitzende Richterin am Landgericht

AVR 95a

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Informatics Corporation
4000 Hollywood Blvd
Suite 333 South
Hollywood
Florida
33021
USA

Holds Certificate No: **FM 636367**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture, distribution, installation and servicing of Laboratory Information Management Systems software for the medical device industry.

For and on behalf of BSI:

Chief Operating Officer Assurance - Americas

Original Registration Date: 2016-05-20
Effective Date: 2018-06-26
Latest Revision Date: 2018-06-26
Expiry Date: 2021-06-25

...making excellence a habit.™

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Occlutech GmbH
Winzerlaer Straße 2, 07745 Jena, Germany

Certified locations:
Winzerlaer Straße 2, 07745 Jena, Germany
Hans-Knöll-Straße 6, 07745 Jena, Germany

Scope of certification:
Design and development, manufacturing and distribution of implantable occluders and corresponding accessories such as pushers, delivery sheaths and sizing balloons.
Distribution of guide wires

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51030-Z4-00.

Certificate registration no.:	51030-14-01	Certificate valid from:	2020-02-15
Validity of previous certificate:	2020-02-14	Certificate valid to:	2023-02-14

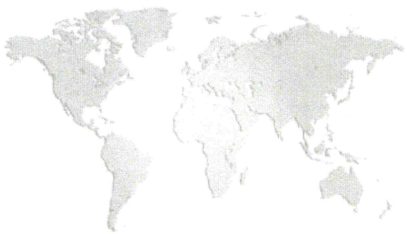
DEKRA Certification GmbH * Stuttgart, Handwerkstraße 15 * DEKRA

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-02-12

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Occlutech GmbH

Winzerlaer Straße 2, 07745 Jena, Germany

Certified location:

Winzerlaer Straße 2, 07745 Jena, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 51030-Z4-00, the decision dated 2020-02-12 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-02-15 to 2024-05-26

Registration No.: 51030-16-04

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-02-12
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 51030-16-04

Valid from 2020-02-15 to 2024-05-26

Revision status of the annex: 0 dated 2020-02-15

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Occlutech® Loader

Class III:

- Figulla® Flex II ASD
- Figulla® Flex II PFO
- Figulla® Flex II UNI
- Occlutech® Occlusions-Pusher
- Occlutech® Sizing Balloon
- Occlutech® Delivery Set

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-02-12
Notified Body ID-number: 0124