EC CERTIFICATE

Number: 2107788CE12

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:
ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto,
Aichi 489-0071
JAPAN

For the product category(ies)

Guide Wires for PTCA and PTA

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them.

0344

Documents, that form the basis of this certificate:

Certification Notice 2107788CN
Addendum, initially dated 15 March 2010

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 15 March 2019
Issued for the first time: 15 March 2010
Reissued: 4 February 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2107788CE12

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Guide Wires for PTCA and PTA

Issued to:

ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto,
Aichi 489-0071
JAPAN

This certificate covers the following product(s):

ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Product Name	Catalog No.	Product Name
AHW14R001S	ASAHI SION 180cm	AHW14R001S	ASAHI SION
AHW14R301S	ASAHI SION 300cm	AHW14R301S	ASAHI SION 300cm
		AHW14R001J	ASAHI SION J
		AHW14R301J	ASAHI SION 300cm J
		AHW14R004S	ASAHI SION blue
		AHW14R304S	ASAHI SION blue 300cm
		AHW14R004J	ASAHI SION blue J
		AHW14R304J	ASAHI SION blue 300cm J

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drs. G.J. Zoetbrood
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ADDENDUM

Belonging to certificate: 2107788CE12

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Guide Wires for PTCA and PTA

Issued to:

ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto,
Aichi 489-0071
JAPAN

This certificate covers the following product(s):

ASAHI PTCA Guide Wire	
Catalog No.	Product Name
APW14R010S	ASAHI SION black
APW14R310S	ASAHI SION black 300cm
APW14R010J	ASAHI SION black J
APW14R310J	ASAHI SION black 300cm J
APW14R010P	ASAHI SION black Pre-shape
APW14R310P	ASAHI SION black 300cm Pre-shape

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ADDENDUM

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CE MARKING OF CONFORMITY
MEDICAL DEVICES

Guide Wires for PTCA and PTA

Issued to:

ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto,
Aichi 489-0071
JAPAN

This certificate covers the following product(s):

ASAHI PTCA Guide Wire	
Catalog No.	Product Name
AHW14R017S	ASAHI SION blue ES
AHW14R317S	ASAHI SION blue ES
AHW14R017J	ASAHI SION blue ES J
AHW14R317J	ASAHI SION blue ES J

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 2107788CE12

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Guide Wires for PTCA and PTA

Issued to:

ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto,
Aichi 489-0071
JAPAN

This certificate covers the following product(s):

ASAHI PTCA Guide Wire	
Catalog No.	Product Name
AHW14R013S	ASAHI SUOH 03
AHW14R013P	ASAHI SUOH 03
AHW14R313S	ASAHI SUOH 03
AHW14R313P	ASAHI SUOH 03

Initial date: 15 March 2010
Revision date: 30 March 2017

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

«LIFE MED» S.R.L. IDNO 1014600035666 SOCIETATEA CU RASPUNDERE LIMITATA REPUBLICA MOLDOVA, mun. CHISINAU

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

Bentley

MANUFACTURER'S DECLARATION OF CONFORMITY

According to the EC – Medical Devices Directive 93/42/EEC, as last amended by Directive 2007/47/EC

FULL QUALITY ASSURANCE PROCEDURE

DECLARATION DE CONFORMITÉ DU FABRICANT

selon la Directive CE 93/42/CEE relative aux dispositifs médicaux modifiée par la directive 2007/47/CE

SYSTÈME COMPLET D'ASSURANCE QUALITÉ

Reference: *Référence:*		**DoC 18-004**	
Manufacturer's Name & Business Address : *Nom du fabricant et adresse postale:*		**Bentley InnoMed GmbH Lotzenäcker 25, 72379 Hechingen, Germany**	
Manufacturing Location: *Adresse de la production:*		**Lotzenäcker 3, 72379 Hechingen, Germany**	
Medical Device Trade Name: *Dénomination commercial du dispositif médical:*		**BeGraft Coronary Stent Graft System**	
Medical Device Generic Name: *Dénomination générique du dispositif médical:*		**Coronary Stent Graft System** *Système d'endoprothèse coronaire couverte*	
Classification: *Classification:*	Class: *Classe:*	III	acc. Annex IX MDD 93/42/EEC, rule: *selon annexe IX DDM 93/42/CEE, règle :* 3
GMDN Code : *Code GMDN:*	*57788*	Term: *Terme:*	*Mesh-sleeve coronary artery stent*
UMDNS Code: *Code UMDNS:*	*17-461*	Term: *Terme:*	*Stent, Vascular*

This declaration is applicable to below listed models/variants (REFs):

La présente déclaration s'applique à tous les lots de références mentionnées ci-dessous :

Stent Diameter / *diamètre stent* [mm]	Stent Length / Longueur stent [mm]					
	8	12	16	18	21	24
2.50	BG08250	BG12250	BG16250	BG18250	BG21250	BG24250
2.75	BG08275	BG12275	BG16275	BG18275	BG21275	BG24275
3.00	BG08300	BG12300	BG16300	BG18300	BG21300	BG24300
3.50	BG08350	BG12350	BG16350	BG18350	BG21350	BG24350
4.00	BG08400	BG12400	BG16400	BG18400	BG21400	BG24400
4.50	n.a.	n.a.	BG16450	BG18450	BG21450	BG24450
5.00	n.a.	n.a.	BG16500	BG18500	BG21500	BG24500

Herewith we declare, under our sole responsibility, that each lot of above mentioned medical device, to which the Full Quality Assurance Procedures have been applied, complies with the applicable provisions of the essential requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

«LIFE MED» S.R.L. IDNO 1014600036656 REPUBLICA MOLDOVA, mun. CHIȘINĂU

Bentley

Nous déclarons sous notre entière responsabilité que chaque lot des dispositifs médicaux mentionnes ci-dessus, auxquels le système complet d'assurance qualité a été appliqué, correspond aux exigences essentielles, aux règles de classification, applicables a toutes les phases, depuis la conception du dispositif jusqu'à 'a son contrôle final avant livraison.

Conformity Assessment Body (acc. MDD 93/42/EEC, Annex XI) *Organisme notifié (selon annexe XI DDM 93/42/CEE)*	Notified Body Number *No de l'Organisme notifié*	Address *Adresse*
MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH	*0482*	*Pilatuspool 2, 20355 Hamburg, Germany*

Certificate Type *Type de certificat*	Certificate Number *No certificat*	Assessment route acc. MDD 93/42/EEC *Procédures d'évaluation de conformité, selon DDM 93/42/CEE*
Full Quality Management System (class I(s), I(m), IIa, IIb, III) *Certificat du Système complet d'assurance qualité (classe I(s), I(m), IIa, IIb, III)*	*7490GB410180410*	*Annex II, excluding section 4* *Annexe II, à l'exclusion de section 4*
Design Examination Certificate (class III devices only) *Certificat d'examen CE de la conception (que pour dispositifs de classe III)*	*13850GB411180410*	*Annex II, section 4* *Annexe II, section 4*

This Declaration is valid until:
La présente déclaration est valable jusqu'au : *June 24th, 2022*

Authorized Signatory:
Signataires autorisés:

Frank Schulte-Hunsbeck
Manager Quality Assurance / Regulatory Affairs

April 12th, 2018
Date

Milisav Obradovic
Site Manager and Technical Director

April 12th, 2018
Date

SOCIETATEA CU RASPUNDERE LIMITATA «LIFE MED» S.R.L. REPUBLICA MOLDOVA, mun. CHIȘINĂU IDNO 1014600035066

CERTIFICAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICA

TÜV SÜD

Product Service

EC-Type Approval Certificate

No. P5 07 11 23579 020

Holder of Certificate: **WIROMA AG**
Schwarzenburgstr. 854
3145 Niederscherli
SWITZERLAND

Product: **PPE for protection against ionizing radiation**
X-ray protective equipment for the user

Model(s): **Clothes for protection against x-ray (61331-3, 5):**
413-AWC, 412-WBT, 421-SDO, 431-LSW with belt
533-DSW with belt, 437-Top, 537-Top, 538 -Skirt
Surgical radiation protection gloves
(61331-3, 7): 466
Thyroid protection:
4534-TS, 4533-TC, 4534 TSV

Parameters:

Optional in the following design:

Outer material:	Nylon and Magic in different colours
Lead equivalent:	0.25, 0.35, 0.50 and 1 mm Pb
Absorption material:	Lead vinyl, X-light© and lead-free
Sizes:	According to the Standard EN 61331-3

This EC-Type Approval Certificate is issued according to Article 8, A, paragraph 4 (PPE of category 3) of Council Directive 89/686/EEC for personal protective equipment. It confirms that the listed product fulfills the basic requirements as specified in Annex II of the Directive. This certificate refers only to the sample submitted to TÜV SÜD Product Service GmbH for testing and certification and on its technical documentation. See also notes overleaf.

Test report no.: 71317085

TÜV SÜD 328217

Date, 2008-01-22

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 89/686/EEC for personal protective equipment, notified by publication in the Official Journal of the EC No. C 203/44 dated July 07th, 1994 with identification No. 0123.

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