

# 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

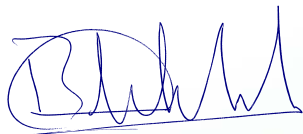
Documents, that form the basis of this certificate:

**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 2024  
Issued for the first time: 15 March 2010  
Reissued: 15 March 2019

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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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](http://www.dekra-certification.com) Company registration 09085396



# ADDENDUM

Belonging to certificate: 2107788CE12

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Guide Wires for PTCA and PTA

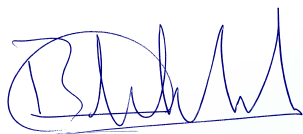
Issued to:

**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		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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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Guide Wires for PTCA and PTA

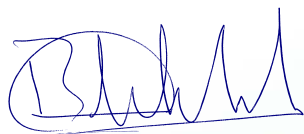
Issued to:

**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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Certification Manager

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Guide Wires for PTCA and PTA

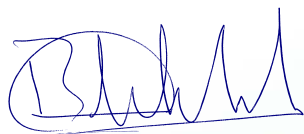
Issued to:

**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

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Guide Wires for PTCA and PTA

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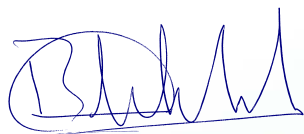
**ASAHI INTECC CO., LTD. Medical Division**  
3-100 Akatsuki-cho, Seto,  
Aichi 489-0071  
JAPAN

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

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