

CERTIFICATE

Number: 2107788DE01

EC DESIGN-EXAMINATION MEDICAL DEVICES

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,
Aichi 489-0071
JAPAN

For the product(s) / product category:

PTCA Guide Wires

Documents, that form the basis of this certificate:

Certification Notice 2107788CN, initially dated 1 June 2008

CE Marking of Conformity 2107788CE01

Addendum, initially dated 1 June 2008

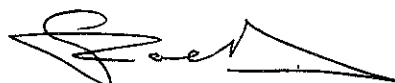
DEKRA hereby certifies that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that the design of the product(s) falling within the product category mentioned above, conforms to the provisions of the Council Directive 93/42/EEC of June 14, 1993, in accordance with Annex II, section 4 of this Directive. The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 12 August 2022

Issued for the first time: 1 June 2008

Reissued: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

1/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

This certificate covers the following product(s):

Series:

PTCA Guide Wire

(ASAHI PTCA GUIDE WIRE and ASAHI PTCA Guide Wire)

- AG series

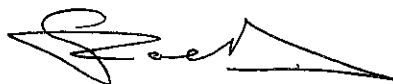
- AGH series

- AGP series

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

2/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

AG Series

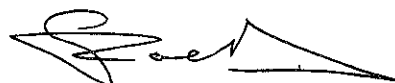
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
12780-01 (AG141000)	ASAHI SOFT 180cm	AG141000	Soft
12780-02 (AG141000J)	ASAHI SOFT 180cm J	AG141000J	Soft J
14939-01 (AG141300)	ASAHI SOFT 300cm	AG141300	Soft 300cm
14939-02 (AG141300J)	ASAHI SOFT 300cm J	AG141300J	Soft 300cm J
12781-01 (AG141002)	ASAHI GRAND SLAM 180cm	AG141002	Grand Slam
12781-02 (AG141002J)	ASAHI GRAND SLAM 180cm J	AG141002J	Grand Slam J
14940-01 (AG141302)	ASAHI GRAND SLAM 300cm	AG141302	Grand Slam 300cm
14940-02 (AG141302J)	ASAHI GRAND SLAM 300cm J	AG141302J	Grand Slam 300cm J

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

3/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

AG Series

Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
12782-01 (AG142000)	ASAHI MEDIUM 180cm	AG142000	Intermediate Medium MEDIUM
- (AG142000J)	ASAHI MEDIUM 180cm J	AG142000J	Intermediate J Medium J MEDIUM J
14941-01 (AG142300)	ASAHI MEDIUM 300cm	AG142300	Intermediate 300cm Medium 300cm MEDIUM 300cm
- (AG142300J)	ASAHI MEDIUM 300cm J	AG142300J	Intermediate 300cm J Medium 300cm J MEDIUM 300cm J
12783-01 (AG143000)	ASAHI STANDARD 180cm	AG143000	Standard
- (AG143000J)	ASAHI STANDARD 180cm J	AG143000J	Standard J
14942-01 (AG143300)	ASAHI STANDARD 300cm	AG143300	Standard 300cm
- (AG143300J)	ASAHI STANDARD 300cm J	AG143300J	Standard 300cm J

Initial date: 1 June 2008,

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

4/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

AG Series

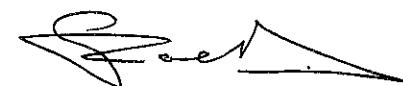
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
12785-01 (AG145000)	ASAHI LIGHT 180cm	AG145000	Light
12785-02 (AG145000J)	ASAHI LIGHT 180cm J	AG145000J	Light J
14944-01 (AG145300)	ASAHI LIGHT 300cm	AG145300	Light 300cm
14944-02 (AG145300J)	ASAHI LIGHT 300cm J	AG145300J	Light 300cm J
12778-01 (AG14M050)	ASAHI MIRACLEbros 3 180cm	AG14M050	Miracle 3 Miraclebros 3 MIRACLEbros 3
- (AG14M050J)	ASAHI MIRACLEbros 3 180cm J	AG14M050J	Miracle 3 J Miraclebros 3 J MIRACLEbros 3 J
14937-01 (AG14M350)	ASAHI MIRACLEbros 3 300cm	AG14M350	Miracle 3 300cm Miraclebros 3 300cm MIRACLEbros 3 300cm
- (AG14M350J)	ASAHI MIRACLEbros 3 300cm J	AG14M350J	Miracle 3 300cm J Miraclebros 3 300cm J MIRACLEbros 3 300cm J

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

5/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

AG Series

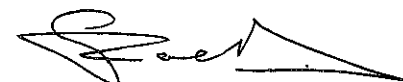
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
12777-01 (AG14M045)	ASAHI MIRACLEbros 4,5 180cm	AG14M045	Miracle 4,5 Miraclebros 4,5 MIRACLEbros 4,5 Miracle 4,5 J Miraclebros 4,5 J MIRACLEbros 4,5 J
- (AG14M045J)	ASAHI MIRACLEbros 4,5 180cm J	AG14M045J	Miraclebros 4,5 J MIRACLEbros 4,5 J Miracle 4,5 300cm Miraclebros 4,5 300cm MIRACLEbros 4,5 300cm Miracle 4,5 300cm J Miraclebros 4,5 300cm J MIRACLEbros 4,5 300cm J
14936-01 (AG14M345)	ASAHI MIRACLEbros 4,5 300cm	AG14M345	Miracle 4,5 300cm Miraclebros 4,5 300cm MIRACLEbros 4,5 300cm Miracle 4,5 300cm J Miraclebros 4,5 300cm J MIRACLEbros 4,5 300cm J
- (AG14M345J)	ASAHI MIRACLEbros 4,5 300cm J	AG14M345J	Miraclebros 4,5 300cm J MIRACLEbros 4,5 300cm J Miracle 6 Miraclebros 6 MIRACLEbros 6 Miracle 6 J Miraclebros 6 J MIRACLEbros 6 J
12779-01 (AG14M060)	ASAHI MIRACLEbros 6 180cm	AG14M060	Miracle 6 Miraclebros 6 MIRACLEbros 6 Miracle 6 J Miraclebros 6 J MIRACLEbros 6 J
- (AG14M060J)	ASAHI MIRACLEbros 6 180cm J	AG14M060J	Miracle 6 J Miraclebros 6 J MIRACLEbros 6 J

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

6/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

AG Series

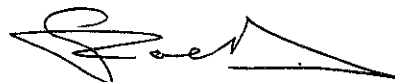
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
14938-01 (AG14M360)	ASAHI MIRACLEbros 6 300cm	AG14M360	Miracle 6 300cm Miraclebros 6 300cm MIRACLEbros 6 300cm Miracle 6 300cm J Miraclebros 6 300cm J MIRACLEbros 6 300cm J
- (AG14M360J)	ASAHI MIRACLEbros 6 300cm J	AG14M360J	Miracle 12 Miraclebros 12 MIRACLEbros 12 Miracle 12 J Miraclebros 12 J MIRACLEbros 12 J
82903-01 (AG14M070)	ASAHI MIRACLEbros 12 180cm	AG14M070	Miracle 12 300cm Miraclebros 12 300cm MIRACLEbros 12 300cm Miracle 12 300cm J Miraclebros 12 300cm J MIRACLEbros 12 300cm J
- (AG14M070J)	ASAHI MIRACLEbros 12 180cm J	AG14M070J	
82903-02 (AG14M370)	ASAHI MIRACLEbros 12 300cm	AG14M370	
- (AG14M370J)	ASAHI MIRACLEbros 12 300cm J	AG14M370J	

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

7/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

**3-100 Akatsuki-cho, Seto,
Aichi 489-0071**

JAPAN

AG Series

Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
12784-01 (AG143090)	ASAHI CONFianza 180cm	AG143090	Conquest Confianza CONFianza
- (AG143090J)	ASAHI CONFianza 180cm J	AG143090J	Conquest J Confianza J CONFianza J
14943-01 (AG143390)	ASAHI CONFianza 300cm	AG143390	Conquest 300cm Confianza 300cm CONFianza 300cm
- (AG143390J)	ASAHI CONFianza 300cm J	AG143390J	Conquest 300cm J Confianza 300cm J CONFianza 300cm J

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

8/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

**3-100 Akatsuki-cho, Seto,
Aichi 489-0071**

JAPAN

AGH Series

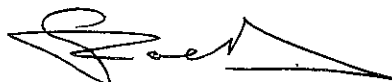
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
20629-01 (AGH143090)	ASAHI CONFIANZA PRO 180cm	AGH143090	Conquest Pro Confianza Pro CONFIANZA PRO
- (AGH143090J)	ASAHI CONFIANZA PRO 180cm J	AGH143090J	Conquest Pro J Confianza Pro J CONFIANZA PRO J
20629-02 (AGH143390)	ASAHI CONFIANZA PRO 300cm	AGH143390	Conquest Pro 300cm Confianza Pro 300cm CONFIANZA PRO 300cm
- (AGH143390J)	ASAHI CONFIANZA PRO 300cm J	AGH143390J	Conquest Pro 300cm J Confianza Pro 300cm J CONFIANZA PRO 300cm J
82902-01 (AGH143091)	ASAHI CONFIANZA PRO 12 180cm	AGH143091	Conquest Pro 12 Confianza Pro 12 CONFIANZA PRO 12
- (AGH143091J)	ASAHI CONFIANZA PRO 12 180cm J	AGH143091J	Conquest Pro 12 J Confianza Pro 12 J CONFIANZA PRO 12 J

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

9/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

AGH Series

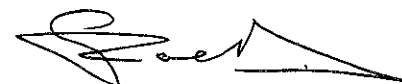
Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
82902-02 (AGH143391)	ASAHI CONFIANZA PRO 12 300cm	AGH143391	Conquest Pro 12 300cm Confianza Pro 12 300cm CONFIANZA PRO 12 300cm
- (AGH143391J)	ASAHI CONFIANZA PRO 12 300cm J	AGH143391J	Conquest Pro 12 300cm J Confianza Pro 12 300cm J CONFIANZA PRO 12 300cm J
12776-01 (AGH146000)	ASAHI PROWATER 180cm	AGH146000	Rinato Prowater PROWATER
12776-02 (AGH146000J)	ASAHI PROWATER 180cm J	AGH146000J	Rinato J Prowater J PROWATER J
14935-01 (AGH146300)	ASAHI PROWATER 300cm	AGH146300	Rinato 300cm Prowater 300cm PROWATER 300cm
14935-02 (AGH146300J)	ASAHI PROWATER 300cm J	AGH146300J	Rinato 300cm J Prowater 300cm J PROWATER 300cm J

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

10/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

**3-100 Akatsuki-cho, Seto,
Aichi 489-0071**

JAPAN

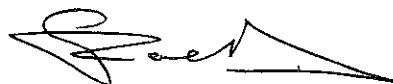
AGH Series

Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
82358-01 (AGH147000)	ASAHI PROWATERflex 180cm	AGH147000	Prowaterflex Route PROWATERflex
82358-11 (AGH147000J)	ASAHI PROWATERflex 180cm J	AGH147000J	Prowaterflex J Route J PROWATERflex J
82358-02 (AGH147300)	ASAHI PROWATERflex 300cm	AGH147300	Prowaterflex 300cm Route 300cm PROWATERflex 300cm
82358-12 (AGH147300J)	ASAHI PROWATERflex 300cm J	AGH147300J	Prowaterflex 300cm J Route 300cm J PROWATERflex 300cm J
		AHW14S003S	ULTIMATEBros 3
		AHW14S003J	ULTIMATEBros 3 J
		AHW14S303S	ULTIMATEBros 3 300cm
		AHW14S303J	ULTIMATEBros 3 300cm J

Initial date: 1 June 2008,
Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2107788DE01

11/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

3-100 Akatsuki-cho, Seto,

Aichi 489-0071

JAPAN

AGP Series

Catalogue Code List:

PTCA Guide Wire			
ASAHI PTCA GUIDE WIRE		ASAHI PTCA Guide Wire	
Catalog No.	Brand Name	Catalog No.	Brand Name
82359-01 (AGP140000)	ASAHI FIELDER 180cm	AGP140000	Fielder
82359-11 (AGP140000J)	ASAHI FIELDER 180cm J	AGP140000J	Fielder J
82359-02 (AGP140300)	ASAHI FIELDER 300cm	AGP140300	Fielder 300cm
82359-12 (AGP140300J)	ASAHI FIELDER 300cm J	AGP140300J	Fielder 300cm J
1011895H (AGP140001)	ASAHI FIELDER FC 180cm	AGP140001	Fielder FC
1011895HJ (AGP140001J)	ASAHI FIELDER FC 180cm J	AGP140001J	Fielder FC J
1011896H (AGP140301)	ASAHI FIELDER FC 300cm	AGP140301	Fielder FC 300cm
1011896HJ (AGP140301J)	ASAHI FIELDER FC 300cm J	AGP140301J	Fielder FC 300cm J
AGP140002	ASAHI FIELDER XT 190cm	AGP140002	Fielder XT
AGP140302	ASAHI FIELDER XT 300cm	AGP140302	Fielder XT 300cm

Initial date: 1 June 2008

Revision date: 12 August 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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