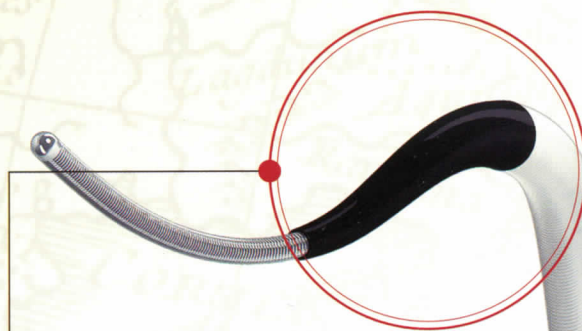


ASAHI Caravel

ASAHI Caravel

A versatile microcatheter that completes the simple and simplifies the complex.



Ultra Low Profile Tip

- Tip tapers to 0.48 mm (0.019" (1.4 Fr))
- Exceptional tip flexibility
- Smoothly tracks into tortuous anatomy



Low Profile Microcatheter

- Excellent crossing profile : 0.62 mm (1.9 Fr)
- Low profile design to cross microchannels
- 2 Caravel fit in a 6Fr guide catheter



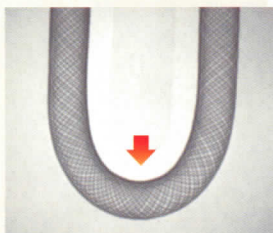
ACT ONE Precision Braided Shaft

- Unique braiding delivers best-in-class flexibility
- Precision engineering ensures unmatched performance in tortuous anatomy

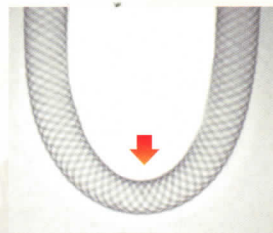
Internal Lumen Integrity

- Enhanced resistance to kinking in tortuous anatomy
- Facilitates optimal guidewire performance

ACT ONE Maintains Inner Lumen



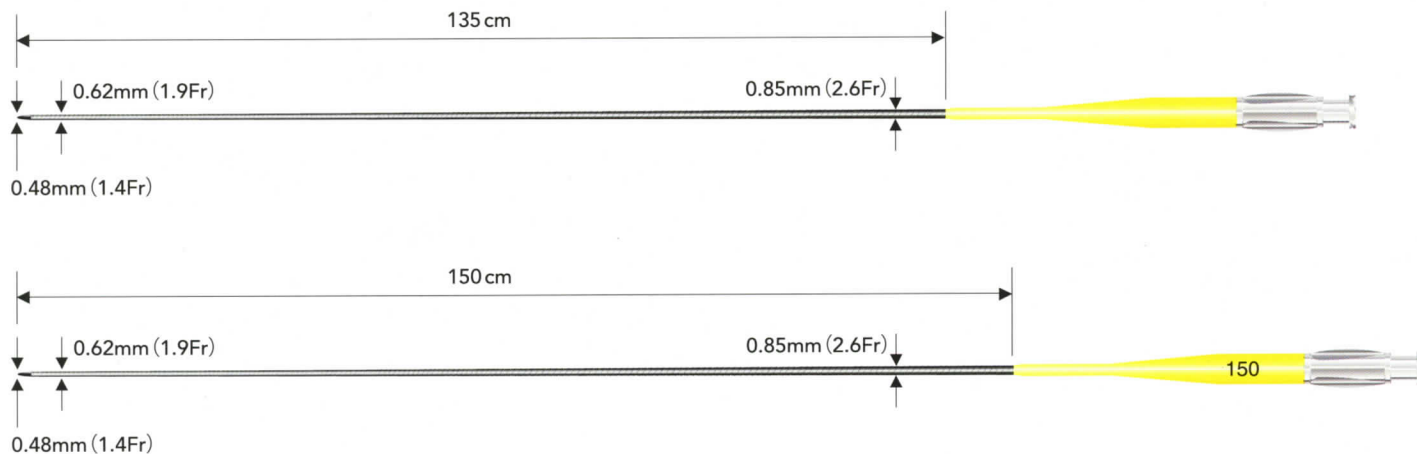
ASAHI Caravel



Competitor "A"

ASAHI Caravel microcatheter is advanced by pushing, not rotating.

Structure & Ordering Information



Product	Catalog No.	Outer Diameter			Inner Diameter		Length	Hydrophilic Coating Length
		Tip	Distal Shaft	Proximal Shaft	Tip	Shaft		
ASAHI Caravel	CRV135-19P	0.48mm (1.4Fr)	0.62mm (1.9Fr)	0.85mm (2.6Fr)	0.40mm (0.016inch)	0.55mm (0.022inch)	135cm	70cm
	CRV150-19P	0.48mm (1.4Fr)	0.62mm (1.9Fr)	0.85mm (2.6Fr)	0.40mm (0.016inch)	0.55mm (0.022inch)	150cm	85cm

Indications for Use

This microcatheter is intended to provide support to facilitate the placement of guidewires in the coronary and peripheral vasculatures, and can be used to exchange one guide wire for another.
This microcatheter is also intended to assist in the delivery of contrast media into the coronary and peripheral vasculatures.
Do not use this microcatheter other than for use in the coronary and peripheral vasculatures.

CE 0344

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Manufactured by:

Distributed by:

ASAHI INTECC

ASAHI INTECC CO.,LTD.

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

Contact phone number: +81-561-86-9101

<http://www.asahi-intecc.com>

DECLARATION OF CONFORMITY (MDD)

1. Name and address of the firm ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

We declare under our sole responsibility that
the medical device

(Name) NEO'S PTCA Guide Wire
 (Series) ASAHI PTCA GUIDE WIRE AG, AGH, and AGP series
 (Model) Refer to Table 1
 (Serial of Lot No.)
 From 8404810031 to
 Name, type or model, batch or serial number, possibly source and number of items

of Class

111

According to annex IX of directive 93/42/EEC:

meets all the provisions of the directive 93/42/EEC which apply it.

- | | | |
|----|---|--|
| 2. | EC Design Examination Certificate No. | 2107788DE01 |
| | Issued by | DEKRA Certification B. V. (Notified under No. 0344) |
| 3. | CE Marking of Conformity Certificate No. | 2107788CE01 |
| | Issued by | DEKRA Certification B. V. (Notified under No. 0344) |
| 4. | Manufacturing Facility | (1) ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN
(2) ASAHI INTECC (THAILAND) CO., LTD.
158/1 Moo 5, Bangkadi Industrial Park Tiwanon Road, Tambol Bangkadi
Amphur Muang Pathumthani 12000 Thailand
(3) ASAHI INTECC HANOI CO., LTD.
THANG LONG Industrial Park Dong Anh District Hanoi Vietnam |
| 5. | Authorized representative in EU | Emergo Europe
Molenstraat 15, 2513 BH, The Hague, The Netherlands |
| 6. | Applied harmonized standards, national standards or other normative documents | Refer to Table 2 and Table 3 |
| 7. | Conformity assessment procedure | Based on Medical Devices Directive 93/42/EEC Annex II.3 and 4 |
| 8. | Signature of Manufacturer | |

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

July 12, 2013

Place, Date

Yoshihiko Fukui,
Executive Director
Senior General Manager
Quality Assurance Division
ASAHI INTECC CO., LTD.

Table 1 Model of ASAHI PTCA GUIDE WIRE

Product No.	Product Name	Product No.	Product Name
12780-01 (AG141000)	ASAHI SOFT 180cm	14939-01 (AG141300)	ASAHI SOFT 300cm
12780-02 (AG141000J)	ASAHI SOFT 180cm J	14939-02 (AG141300J)	ASAHI SOFT 300cm J
12781-01 (AG141002)	ASAHI GRAND SLAM 180cm	14940-01 (AG141302)	ASAHI GRAND SLAM 300cm
12781-02 (AG141002J)	ASAHI GRAND SLAM 180cm J	14940-02 (AG141302J)	ASAHI GRAND SLAM 300cm J
12782-01 (AG142000)	ASAHI MEDIUM 180cm	14941-01 (AG142300)	ASAHI MEDIUM 300cm
- (AG142000J)	ASAHI MEDIUM 180cm J	- (AG142300J)	ASAHI MEDIUM 300cm J
12783-01 (AG143000)	ASAHI STANDARD 180cm	14942-01 (AG143300)	ASAHI STANDARD 300cm
- (AG143000J)	ASAHI STANDARD 180cm J	- (AG143300J)	ASAHI STANDARD 300cm J
12785-01 (AG145000)	ASAHI LIGHT 180cm	14944-01 (AG145300)	ASAHI LIGHT 300cm
12785-02 (AG145000J)	ASAHI LIGHT 180cm J	14944-02 (AG145300J)	ASAHI LIGHT 300cm J
12778-01 (AG14M050)	ASAHI MIRACLEbros 3 180cm	14937-01 (AG14M350)	ASAHI MIRACLEbros 3 300cm
- (AG14M050J)	ASAHI MIRACLEbros 3 180cm J	- (AG14M350J)	ASAHI MIRACLEbros 3 300cm J
12777-01 (AG14M045)	ASAHI MIRACLEbros 4.5 180cm	14936-01 (AG14M345)	ASAHI MIRACLEbros 4.5 300cm
- (AG14M045J)	ASAHI MIRACLEbros 4.5 180cm J	- (AG14M345J)	ASAHI MIRACLEbros 4.5 300cm J
12779-01 (AG14M060)	ASAHI MIRACLEbros 6 180cm	14938-01 (AG14M360)	ASAHI MIRACLEbros 6 300cm
- (AG14M060J)	ASAHI MIRACLEbros 6 180cm J	- (AG14M360J)	ASAHI MIRACLEbros 6 300cm J
82903-01 (AG14M070)	ASAHI MIRACLEbros 12 180cm	82903-02 (AG14M370)	ASAHI MIRACLEbros 12 300cm
- (AG14M070J)	ASAHI MIRACLEbros 12 180cm J	- (AG14M370J)	ASAHI MIRACLEbros 12 300cm J
12784-01 (AG143090)	ASAHI CONFIANZA 180cm	14943-01 (AG143390)	ASAHI CONFIANZA 300cm
- (AG143090J)	ASAHI CONFIANZA 180cm J	- (AG143390J)	ASAHI CONFIANZA 300cm J
20629-01 (AGH143090)	ASAHI CONFIANZA PRO 180cm	20629-02 (AGH143390)	ASAHI CONFIANZA PRO 300cm
- (AGH143090J)	ASAHI CONFIANZA PRO 180cm J	- (AGH143390J)	ASAHI CONFIANZA PRO 300cm J
82902-01 (AGH143091)	ASAHI CONFIANZA PRO 12 180cm	82902-02 (AGH143391)	ASAHI CONFIANZA PRO 12 300cm
- (AGH143091J)	ASAHI CONFIANZA PRO 12 180cm J	- (AGH143391J)	ASAHI CONFIANZA PRO 12 300cm J
12776-01 (AGH146000)	ASAHI PROWATER 180cm	14935-01 (AGH146300)	ASAHI PROWATER 300cm
12776-02 (AGH146000J)	ASAHI PROWATER 180cm J	14935-02 (AGH146300J)	ASAHI PROWATER 300cm J
82358-01 (AGH147000)	ASAHI PROWATERflex 180cm	82358-02 (AGH147300)	ASAHI PROWATERflex 300cm
82358-11 (AGH147000J)	ASAHI PROWATERflex 180cm J	82358-12 (AGH147300J)	ASAHI PROWATERflex 300cm J
82359-01 (AGP140000)	ASAHI FIELDER 180cm	82359-02 (AGP140300)	ASAHI FIELDER 300cm
82359-11 (AGP140000J)	ASAHI FIELDER 180cm J	82359-12 (AGP140300J)	ASAHI FIELDER 300cm J

Product No.	Product Name	Product No.	Product Name
1011895H (AGP140001)	ASAHI FIELDER FC 180cm	1011896H (AGP140301)	ASAHI FIELDER FC 300cm
1011895HJ (AGP140001J)	ASAHI FIELDER FC 180cm J	1011896HJ (AGP140301J)	ASAHI FIELDER FC 300cm J
AGP140002	ASAHI FIELDER XT 190cm	AGP140302	ASAHI FIELDER XT 300cm

Table 2 Applied harmonized standards (QA-Related Standards)

Standard Reference	Title
EN ISO 13485:2012 AC:2012 ISO 13485:2003 Cor1:2009	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EC Directive 93/42/EEC L 169 1993 Amd 1: 1998 Amd 2: 2000 Amd 3: 2002 Amd 4: 2003 Amd 5: 2007	Medical Devices Directive (2007)

Table 3 Applied harmonized standards (Product related standards)

Standard Reference	Title
EN 556-1:2001 AC: 2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- Part 1: Requirements for terminally sterilized medical devices
EN 556-2: 2003	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- Part 2: Requirements for aseptically processed medical devices
EN ISO 15223-1: 2012 ISO 15223-1: 2012	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied –Part1: General requirements
EN 1041:2008	Terminology, symbols and information provided with medical devices - Information Supplied by the Manufacturer
EN ISO 10993-1: 2009 AC: 2010 ISO 10993-1: 2009 Cor1: 2010	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-2: 2006 ISO 10993-2: 2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements – Second Edition
EN ISO 10993-4: 2009 ISO 10993-4: 2002 Amd 1: 2006	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood AMENDMENT 1
EN ISO 10993-5: 2009 ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for cytotoxicity: <i>in vitro</i> methods
EN ISO 10993-7: 2008 AC:2009 ISO 10993-7: 2008 Cor1:2009	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10: 2010 ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization

Standard Reference	Title
EN ISO 10993-11: 2009 ISO 10993-11: 2006	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12: 2012 ISO 10993-12: 2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 11070: 1999 ISO 11070: 1998	Sterile, single-use intravascular catheter introducers
EN ISO 11135-1:2007 ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1:Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-1: 2006 ISO11138-1: 2006	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2: 2009 ISO 11138-2: 2006	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1: 2009 ISO 11607-1: 2006	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems-First edition
EN ISO 11607-2: 2006 ISO 11607-2: 2006	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes-First edition
EN ISO 11737-1: 2006 AC:2009 ISO 11737-1: 2006 Cor 1: 2007	Sterilization of medical devices – Microbiological methods – Part 1: Estimation of population of microorganisms on products Corrigendum 1
EN ISO 11737-2: 2009 ISO 11737-2: 2009	Sterilization of medical devices – Microbiological methods -- Part 2: Tests of sterility performed in the validation of a sterilization process
EN ISO 14155: 2011 AC:2011 ISO 14155: 2011 Cor1:2011	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 14161: 2009 ISO 14161: 2009	Sterilization of Health Care Products - Biological Indicators - Guidance for the Selection, Use and Interpretation of Results-First Edition
EN ISO 14644-1: 1999 ISO 14644-1: 1999	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness-First Edition
EN ISO 14644-2: 2000 ISO 14644-2: 2000	Cleanrooms and Associated Controlled Environments - Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1-First Edition
EN ISO 14644-3: 2005 ISO 14644-3: 2005	Cleanrooms and associated controlled environments - Part 3: Test methods-First Edition
EN ISO 14698-1: 2003 ISO 14698-1: 2003	Cleanrooms and associated controlled environments Biocontamination control - Part 1: General principles and methods - First Edition
EN ISO 14698-2: 2003 AC: 2006 ISO 14698-2: 2003 Cor1: 2004	Cleanrooms and associated controlled environments Biocontamination control - Part 1: General principles and methods - First Edition
EN ISO 14971: 2012 ISO 14971: 2007	Medical device – Application of risk management to medical devices
MEDDEV. 2.12-1: 2013	GUIDELINES ON A MEDICAL DEVICE VIGILANCE SYSTEM
MEDDEV. 2.7.1: 2009	EVALUATION OF CLINICAL DATA: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
MEDDEV. 2.12-2: 2012	POST MARKET CLINICAL FOLLOW-UP STUDIES

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

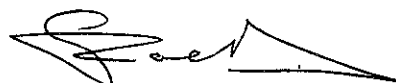
DEKRA hereby certifies that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that the design of the product(s) falling 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

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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

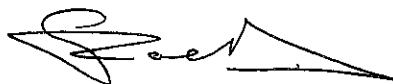
- AGH series

- 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

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ADDENDUM

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2/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

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AG Series

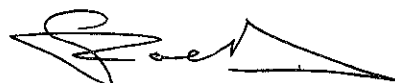
Catalogue Code List:

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

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drs. G.J. Zoetbrood
Managing Director



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Certification Manager

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ADDENDUM

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3/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

Issued to:

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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

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Managing Director



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EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

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AG Series

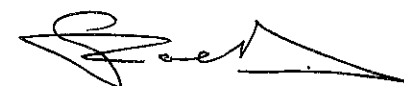
Catalogue Code List:

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

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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

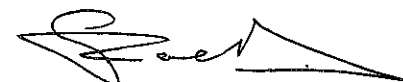
Catalogue Code List:

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

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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

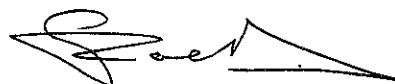
Catalogue Code List:

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

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ADDENDUM

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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

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Managing Director



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EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

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AGH Series

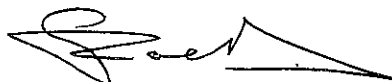
Catalogue Code List:

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

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AGH Series

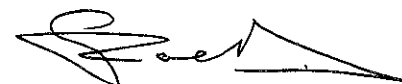
Catalogue Code List:

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

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EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

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JAPAN

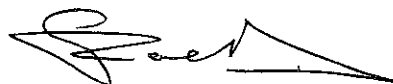
AGH Series

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

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11/11

EC DESIGN-EXAMINATION MEDICAL DEVICES

PTCA Guide Wires

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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

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

ASAHI INTECC (THAILAND) CO.,LTD.
158/1 Moo 5, Bangkadi Industrial Park,
Tiwanon Road, Tambol Bangkadi,
Amphur Muang Pathumthani,
Pathumthani
12000
Thailand

Holds Certificate Number:

MD 718537

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

The Design and development, Manufacturing and EtO sterilization of Catheters, and Guidewires.
The Manufacturing and EtO sterilization of Electrosurgical snares for use in endoscopy.
The Design and development, and Manufacturing of metallic wires, metallic wire-ropes and metallic coils for medical devices.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2008-06-01

Latest Revision Date: 2021-05-14

Effective Date: 2020-03-25

Expiry Date: 2023-03-24

Page: 1 of 2



003

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 718537**

Location	Registered Activities
ASAHI INTECC (THAILAND) CO.,LTD. N1 Factory / N2 Factory 142/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand	The Design and development, Manufacturing and EtO sterilization of Catheters, and Guidewires. The Manufacturing and EtO sterilization of Electrosurgical snares for use in endoscopy. The Design and development, and Manufacturing of metallic wires, metallic wire-ropes and metallic coils for medical devices.
ASAHI INTECC (THAILAND) CO.,LTD. 158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand	The Design and development, Manufacturing and EtO sterilization of Catheters, and Guidewires. The Manufacturing and EtO sterilization of Electrosurgical snares for use in endoscopy.
ASAHI INTECC (THAILAND) CO.,LTD. N3 Factory, 149 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand	The Design and development.

Original Registration Date: 2008-06-01

Latest Revision Date: 2021-05-14

Effective Date: 2020-03-25

Expiry Date: 2023-03-24

Page: 2 of 2

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