

EC CERTIFICATE

Number: 2107788CE11

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)

Peripheral Guide Wires

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 29 January 2009

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: 1 February 2023
Issued for the first time: 29 January 2009
Reissued: 1 February 2018

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: 2107788CE11

1/4

CE MARKING OF CONFORMITY MEDICAL DEVICES

Peripheral 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):

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
Treasure 12	PAGH18M070	ASAHI Peripheral Guide Wire Treasure 12
	PAGH18M370	ASAHI Peripheral Guide Wire Treasure 12 300cm
Astat 30	PAGH18M071	ASAHI Peripheral Guide Wire Astat 30
	PAGH18M371	ASAHI Peripheral Guide Wire Astat 30 300cm
Regalia XS 1.0	PAGP140000	ASAHI Peripheral Guide Wire Regalia XS 1.0
	PAGP140300	ASAHI Peripheral Guide Wire Regalia XS 1.0 300cm
Astat XS 20	PAGH143092	ASAHI Peripheral Guide Wire Astat XS 20
	PAGH143392	ASAHI Peripheral Guide Wire Astat XS 20 300cm
Treasure Floppy	PAGH18M072	ASAHI Peripheral Guide Wire Treasure Floppy
	PAGH18M372	ASAHI Peripheral Guide Wire Treasure Floppy 300cm

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: 2107788CE11

2/4

CE MARKING OF CONFORMITY MEDICAL DEVICES

Peripheral Guide Wires

Issued to:

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

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
ASAHI Gladius	PPW14R100S	ASAHI Peripheral Guide Wire ASAHl Gladius
	PPW14R200S	
	PPW14R300S	
	PPW18R100S	
	PPW18R200S	
	PPW18R300S	
	PPW14R100P	
	PPW14R200P	
	PPW14R300P	
	PPW18R100P	
	PPW18R200P	
	PPW18R300P	

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: 2107788CE11

3/4

CE MARKING OF CONFORMITY MEDICAL DEVICES

Peripheral Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

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

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
ASAHI Halberd	PHW14R101S	ASAHI Peripheral Guide Wire ASAHI Halberd
	PHW14R201S	
	PHW14R301S	
	PHW18R101S	
	PHW18R201S	
	PHW18R301S	
	PHW14R101P	
	PHW14R201P	
	PHW14R301P	
	PHW18R101P	
	PHW18R201P	
	PHW18R301P	

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: 2107788CE11

4/4

CE MARKING OF CONFORMITY MEDICAL DEVICES

Peripheral Guide Wires

Issued to:

ASAHI INTECC CO., LTD. Medical Division

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

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
ASAHI Gaia PV	PHW18R102S PHW18R202S PHW18R302S PHW18R102P PHW18R202P PHW18R302P	ASAHI Peripheral Guide Wire ASahi Gaia PV
Astato XS 40	PAGHW143094 PAGHW143394	ASAHI Peripheral Guide Wire Astato XS 40

Initial date: 29 January 2009

Revision date: 16 May 2016

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

Certificate of Registration

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

This is to certify that:

ASAHI INTECC HANOI CO., LTD.
Thang Long Industrial Park,
Dong Anh District,
Hanoi,
Vietnam

Holds Certificate Number:

MD 718982

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, development, manufacture, EtO sterilization and distribution of Catheters and Guidewires



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-12-28

Latest Revision Date: 2021-07-08

Effective Date: 2021-07-08

Expiry Date: 2024-07-07

Page: 1 of 2



...making excellence a habit.™

Certificate No: **MD 718982**

Location	Registered Activities
ASAHI INTECC HANOI CO., LTD. Thang Long Industrial Park, Dong Anh District, Hanoi, Vietnam	The design, development, manufacture and distribution activities of Catheter and Guidewire including EtO gas sterilization. The manufacture of PTFE coated component and microbiological testing are performed



Original Registration Date: 2019-12-28

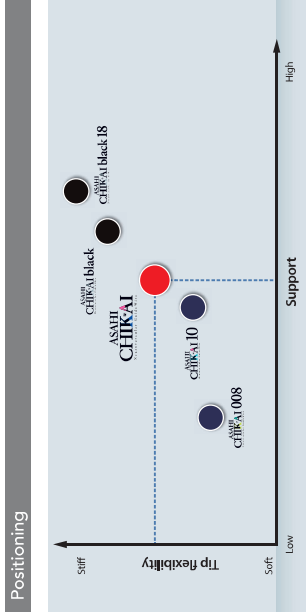
Effective Date: 2021-07-08

Latest Revision Date: 2021-07-08

Expiry Date: 2024-07-07

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:
BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.



normal vessels / standard cases

ASAHI CHIKAI

tiny vessels / precision cases

ASAHI CHIKAI 10
ASAHI CHIKAI 008

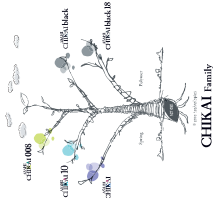
tortuous vessels / complex cases

ASAHI CHIKAI black

large vessels / high support cases

ASAHI CHIKAI black 18

Specification & ordering information						
Product	Catalog No.	O.D.	Coating	Usable length	Coil length	Tip shape
ASAHI CHIKAI 008	WAN-CH008-200	0.20 (0.26mm) (0.205 (0.210mm))	Hydrophilic coating (SIP-COAT™) 180mm	200mm	8mm	Straight
	WAN-CH016-200	0.26mm (0.270mm)	Hydrophilic coating (SIP-COAT™) 170mm	200mm	9.5mm	Straight
	WAN-CH016-300	0.26mm (0.270mm)	Hydrophilic coating (SIP-COAT™) 170mm	300mm	9.5mm	Straight
ASAHI CHIKAI	WAN-CH030-200	0.26mm (0.2714mm)	Hydrophilic coating (SIP-COAT™) 170mm	200mm	30mm	Straight
	WAN-CH030-300	0.26mm (0.2714mm)	Hydrophilic coating (SIP-COAT™) 170mm	300mm	30mm	Straight
	WAN-CH030-400	0.26mm (0.2714mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight
ASAHI CHIKAI black	WAN-CH030-400	0.26mm (0.2714mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight
	WAN-CH030-400	0.26mm (0.2714mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight
	WAN-CH030-400	0.26mm (0.2714mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight
ASAHI CHIKAI black 18	WAN-CH030-400	0.26mm (0.2714mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight
	WAN-CH030-400	0.26mm (0.2714mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight
	WAN-CH030-400	0.26mm (0.2714mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight



Not all names and figures are available in all countries. Please check carefully with your sales representative.
Control with S.P. (CE) mark.

Manufactured by: **ASAHI INTECC**
9-1100 Aikawa-cho, Saito, Aichi 486-0271 Japan
Contact phone number: +81-561-466-0101
<http://www.asahi-intecc.com>

Distributed by: **ASAHI INTECC**

Your dreams. Woven together.
ASAHI INTECC

ASAHI CHIKAI Family ver.1 (MARCH 2012)

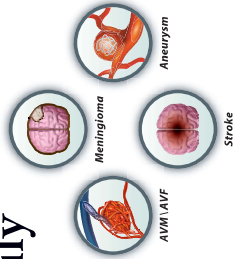
ASAHI CHIKAI Family

Neurovascular Guidewire

ASAHI CHIKAI Family

Providing good torque response, support and durability for neuro interventional procedures

ASAHI CHIKAI family of guide wires has been originally developed based on Asahi Intecc's unique set of technologies which accomplished great success in the field of cardiovascular interventions.



Technologies with Dual-coil design using ACT ONE

Employs the ASAHI brand rope coil which provides torqueability, flexibility and resiliency. ASAHI INTECC CO., LTD's unique technologies in wire drawing, wire forming, torque transmission and coating are utilized to create highly responsive guide wires featuring ASAHI's ACT ONE dual-coil design.



Key features

- Precise torque response**
 - ACT ONE provides exceptional torque response in tortuous anatomy.
- Durable tip-shape retention**
 - Incorporating with ACT ONE, re-shapable pre-shaped round curve and 90 degree angle enhance tip shape memory and durability.



Round curve
#Available for CHIKAI
CHIKAI black and CHIKAI blue is

Angled 90°
#Available for CHIKAI black

ASAHI CHIKAI

Neurovascular GuideWire

ASAHI CHIKAI, ASAHI CHIKAI T10 and ASAHI CHIKAI 008 are designed for an optimal balance between tip flexibility and microcatheter support



ASAHI CHIKAI 008 (200cm)

— Soft flexible tip & distal body



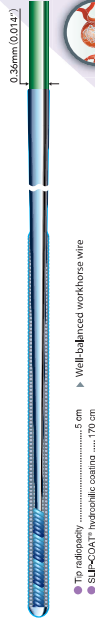
ASAHI CHIKAI T10 (200cm, 300cm)

— Balanced tip and higher body support



ASAHI CHIKAI (200cm, 300cm)

— 0.36mm (0.014") workhorse guide wire



ASAHI CHIKAI black

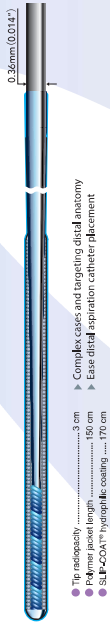
Neurovascular GuideWire

Providing excellent support and less friction due to polymer jacket and hydrophilic coating for smooth delivery of microcatheter



ASAHI CHIKAI black (200cm)

— 0.36mm (0.014") guide wire with enhanced lubricity



ASAHI CHIKAI black 18 (200cm)

— Specialty guide wire

