

# ASAHI

## *Peripheral Guide Wire*

New Guide Wires

ASAHI **Gladius**    ASAHI **Halberd**  
ASAHI **Gaia PV**    **Astato XS 40**

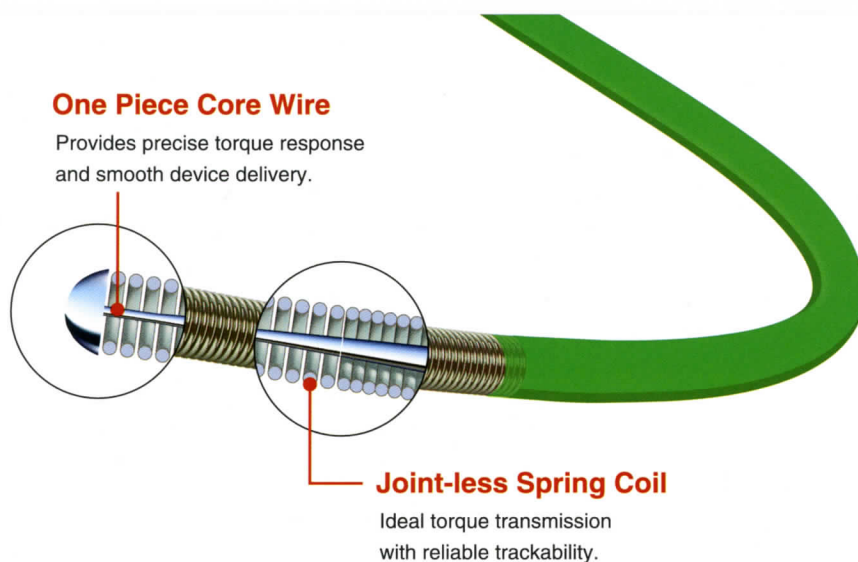
ASAHI's unique guide wire technology with Composite Core

**SION TECC**   
Leading to the NEXT

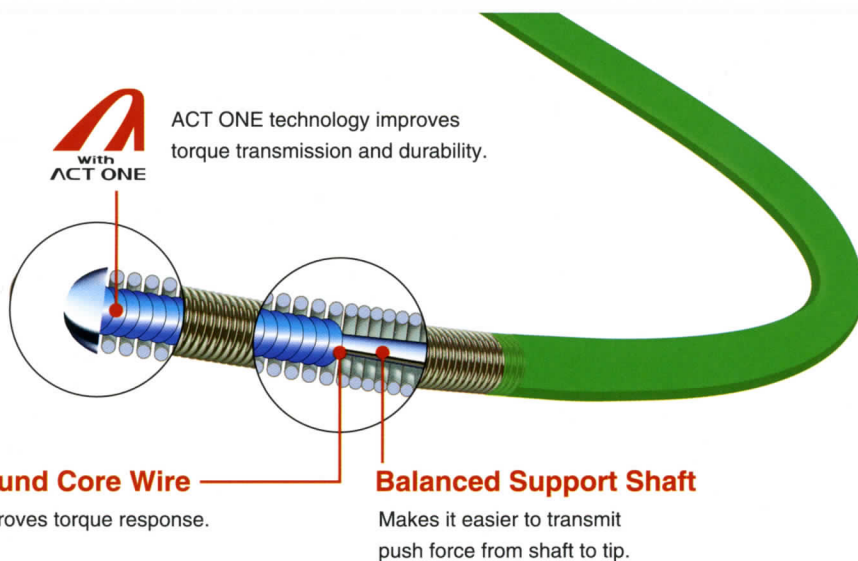
# ASAHI

## *Peripheral Guide Wire*

Exceptional guide wires for precise interventions.



**Regalia  
Treasure  
Astato**



ASAHI's unique guide wire technology with Composite Core  
**SION TECC**   
Leading to the NEXT

ASAHI **Gladius**  
ASAHI **Halberd**  
ASAHI **Gaia PV**

## Frontline

### Regalia XS 1.0

0.36mm (0.014inch) Sub-total/Tortuous



Support ● ● ○ ○ ○  
Torque ● ○ ○ ○ ○  
Penetration ● ○ ○ ○ ○

Balanced lubricity and trackability for BTK procedures.

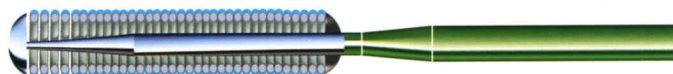
Tip Load  
**1.0 G**

Polymer Jacket

### Treasure Floppy

0.46mm (0.018inch)

Workhorse



Support ● ● ○ ○ ○  
Torque ● ● ○ ○ ○  
Penetration ● ● ○ ○ ○

Precise handling with a flexible tip for tortuous anatomy.

Tip Load  
**4.0 G**

Hybrid Coating  
Silicone/Hydrophilic

## Specialty

### ASAHI Halberd

0.36mm (0.014inch)

Complex Lesion



Support ● ● ● ○ ○  
Torque ● ● ● ● ○  
Penetration ● ● ● ● ●

Composite core improves torque for navigation, and the micro-cone tip improves penetration.

Tip Load  
**12.0 G**

Hydrophilic Coating  
Uncoated Ball Tip

WITH ACT ONE

Micro-cone Tip

### Treasure 12

0.46mm (0.018inch)

Complex Lesion



Support ● ● ○ ○ ○  
Torque ● ● ● ● ○  
Penetration ● ● ○ ○ ○

Consistent response and tactile feedback for complex lesion navigation.

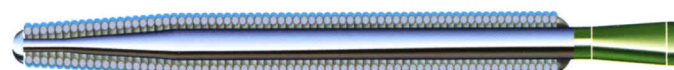
Tip Load  
**12.0 G**

Hydrophilic Coating  
Uncoated Ball Tip

### Astato XS 20

0.36mm (0.014inch)

Highly Calcified Lesion



Support ● ● ○ ○ ○  
Torque ● ● ● ● ○  
Penetration ● ● ● ● ●

Tapered tip provides excellent penetration.

Tip Load  
**20.0 G**

Hydrophilic Coating  
Uncoated Ball Tip

Tapered

### Astato 30

0.46mm (0.018inch)

Highly Calcified Lesion



Support ● ● ● ○ ○  
Torque ● ● ● ● ○  
Penetration ● ● ● ● ●

Tapered tip provides excellent penetration.

Tip Load  
**30.0 G**

Hydrophilic Coating  
Uncoated Ball Tip

Tapered



## ASAHI Gladius 0.36mm (0.014inch)

Workhorse



Support	● ● ○ ○ ○	Composite core improves tip durability and torque to treat lesions in multiple vessels.
Torque	● ● ● ○ ○	
Penetration	● ● ○ ○ ○	

Tip Load  
**3.0 G**

Polymer Jacket



## ASAHI Gladius 0.46mm (0.018inch)

Workhorse



Support	● ● ● ● ●	Composite core improves torque response with increased support for device delivery.
Torque	● ● ● ○ ○	
Penetration	● ● ○ ○ ○	

Tip Load  
**4.0 G**

Polymer Jacket



## ASAHI Halberd 0.46mm (0.018inch)

Complex Lesion



Support	● ● ● ● ○	Composite core provides precise torque for navigation with more support and micro-cone tip for proximal cap penetration.
Torque	● ● ● ● ●	
Penetration	● ● ● ● ○	

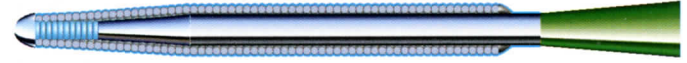
Tip Load  
**12.0 G**

Hydrophilic Coating  
Uncoated Ball Tip



## ASAHI Gaia PV 0.46mm (0.018inch)

Complex Lesion



Support	● ● ● ● ○	Composite core with a lower tip load improves navigation and torque. The tapered coil and micro-cone tip makes it easier to advance.
Torque	● ● ● ● ●	
Penetration	● ● ● ● ○	

Tip Load  
**7.5 G**

Hydrophilic Coating  
Uncoated Ball Tip



## Astato XS 40 0.36mm (0.014inch)

Highly Calcified Lesion



Support	● ● ○ ○ ○	Tapered tip provides excellent penetration.
Torque	● ● ● ● ○	
Penetration	★ ★ ★ ★ ★	

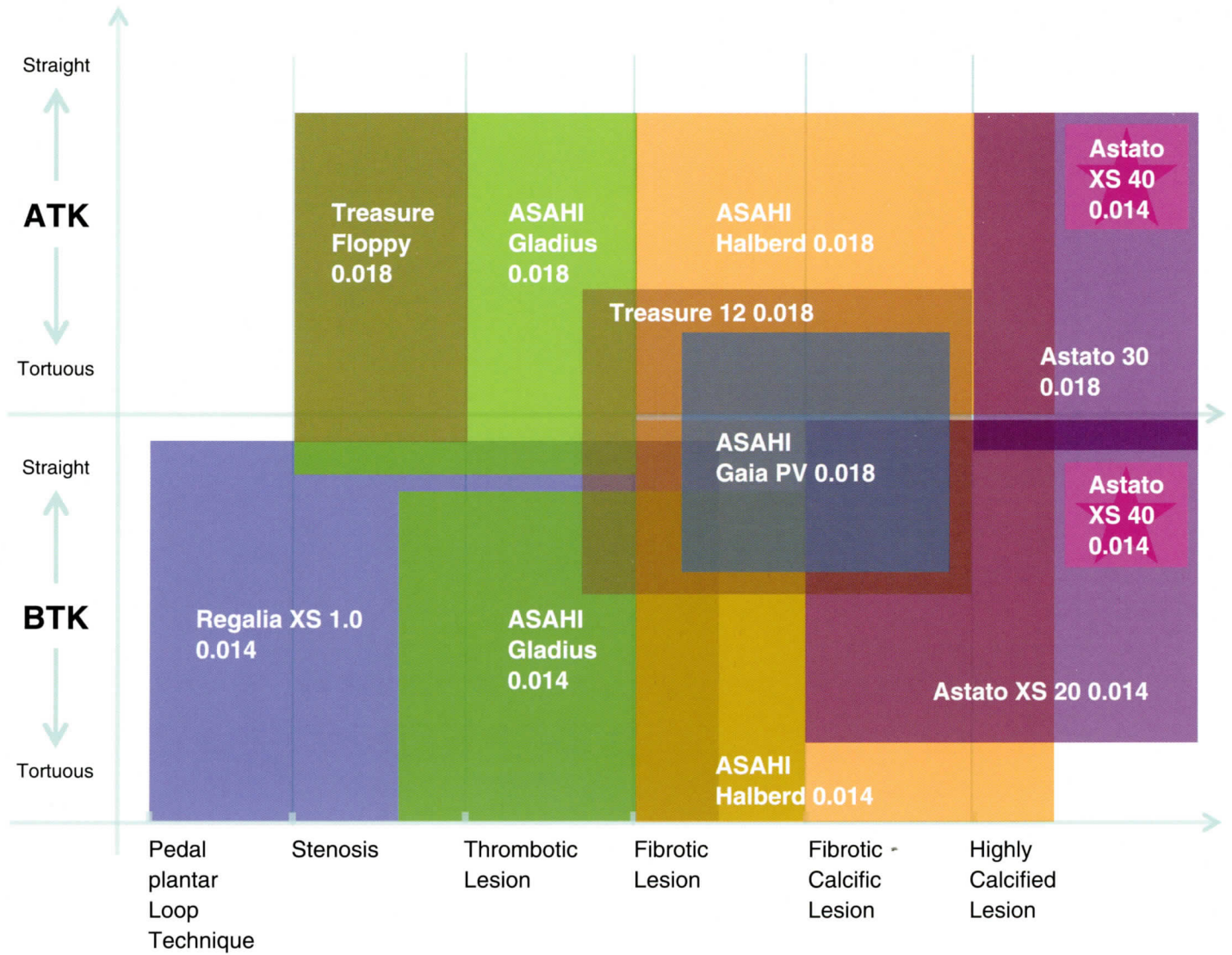
Tip Load  
**40.0 G**

Hydrophilic Coating  
Uncoated Ball Tip





## Wire Selection Chart



# Ordering Information

Product	Diameter	Catalog No.	Length	SION TECC	Tip Shape
ASAHI Gladius	0.36mm (0.014inch)	PPW14R100S	200 <sub>cm</sub>	SION TECC	Straight
		PPW14R200S	235 <sub>cm</sub>		
		PPW14R300S	300 <sub>cm</sub>		
	0.36mm (0.014inch)	PPW14R100P	200 <sub>cm</sub>		Pre-shaped
		PPW14R200P	235 <sub>cm</sub>		
		PPW14R300P	300 <sub>cm</sub>		
	0.46mm (0.018inch)	PPW18R100S	200 <sub>cm</sub>		Straight
		PPW18R200S	235 <sub>cm</sub>		
		PPW18R300S	300 <sub>cm</sub>		
ASAHI Halberd	0.36mm (0.014inch)	PHW14R101S	200 <sub>cm</sub>	SION TECC	Straight
		PHW14R201S	235 <sub>cm</sub>		
		PHW14R301S	300 <sub>cm</sub>		
	0.36mm (0.014inch)	PHW14R101P	200 <sub>cm</sub>		Pre-shaped
		PHW14R201P	235 <sub>cm</sub>		
		PHW14R301P	300 <sub>cm</sub>		
	0.46mm (0.018inch)	PHW18R101S	200 <sub>cm</sub>		Straight
		PHW18R201S	235 <sub>cm</sub>		
		PHW18R301S	300 <sub>cm</sub>		
	0.46mm (0.018inch)	PHW18R101P	200 <sub>cm</sub>		Pre-shaped
		PHW18R201P	235 <sub>cm</sub>		
		PHW18R301P	300 <sub>cm</sub>		
ASAHI Gaia PV	0.46mm (0.018inch)	PHW18R102S	200 <sub>cm</sub>	SION TECC	Straight
		PHW18R202S	235 <sub>cm</sub>		
		PHW18R302S	300 <sub>cm</sub>		
	0.46mm (0.018inch)	PHW18R102P	200 <sub>cm</sub>		Pre-shaped
		PHW18R202P	235 <sub>cm</sub>		
		PHW18R302P	300 <sub>cm</sub>		
Regalia XS 1.0	0.36mm (0.014inch)	PAGP140000	180 <sub>cm</sub>		Straight
		PAGP140300	300 <sub>cm</sub>		
Astato XS 20	0.36mm (0.014inch)	PAGH143092	180 <sub>cm</sub>		
		PAGH143392	300 <sub>cm</sub>		
Astato XS 40	0.36mm (0.014inch)	PAGHW143094	200 <sub>cm</sub>		
		PAGHW143394	300 <sub>cm</sub>		
Astato 30	0.46mm (0.018inch)	PAGH18M071	180 <sub>cm</sub>		
		PAGH18M371	300 <sub>cm</sub>		
Treasure Floppy	0.46mm (0.018inch)	PAGH18M072	190 <sub>cm</sub>		
		PAGH18M372	300 <sub>cm</sub>		
Treasure 12	0.46mm (0.018inch)	PAGH18M070	180 <sub>cm</sub>		
		PAGH18M370	300 <sub>cm</sub>		

## Indications for Use

This Product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures.  
This device is intended for peripheral vascular use only.

Not all shapes and sizes are available in all markets. Please check availability with your sales representative.  
Coated with SLIP-COAT® coating.

CE 0344

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"ASAHI", "Astato", "ASAHI Gaia", "ASAHI Gladius" and "Treasure" are trademarks or registered trademarks of ASAHI INTECC CO., LTD. in Japan and other countries.

Manufactured 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>

Distributed by:

**Brage**  
MEDICAL



## 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) Peripheral Guide Wires  
(Model) ASAHI Peripheral Guide Wire (Refer to Table 1 in page 2/4)  
(Serial of Lot No.) From 93075-10642 to  
Name, type or model, batch or serial number, possibly source and number of items

of Class

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

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

2. CE Marking of Conformity Certificate No.

2107788CE11

Issued by

DEKRA Certification B. V. (Notified under No. 0344)

3. 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

4. Authorized representative in EU

Emergo Europe  
Molenstraat 15, 2513 BH, The Hague, The Netherlands

5. Applied harmonized standards, national standards or other normative documents

Refer to Table 2 in page 3/4-4/4

6. Conformity assessment procedure

Based on Medical Devices Directive 93/42/EEC Annex II.3

7. Signature of Manufacturer

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

June 23, 2014

Place, Date

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



**Table 1. Model of ASAHI Peripheral Guide Wire**

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
Treasure12	PAGH18M070	ASAHI Peripheral Guide Wire Treasure 12
	PAGH18M370	ASAHI Peripheral Guide Wire Treasure 12 300cm
Atrato 30	PAGH18M071	ASAHI Peripheral Guide Wire Atrato 30
	PAGH18M371	ASAHI Peripheral Guide Wire Atrato 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
Atrato XS 20	PAGH143092	ASAHI Peripheral Guide Wire Atrato XS 20
	PAGH143392	ASAHI Peripheral Guide Wire Atrato XS 20 300cm
Treasure Floppy	PAGH18M072	ASAHI Peripheral Guide Wire Treasure Floppy
	PAGH18M372	ASAHI Peripheral Guide Wire Treasure Floppy 300cm

**Table 2. Applied harmonized standards****1. QA-RELATED STANDARDS**

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

**2. PRODUCT-RELATED STANDARDS**

Standard Reference	Title
<b>EN 556-1: 2001</b> <b>AC: 2006</b>	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- Part 1: Requirements for terminally sterilized medical devices
<b>EN 556-2: 2003</b>	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- Part 2: Requirements for aseptically processed medical devices
<b>EN ISO 15223-1: 2012</b> <b>ISO 15223-1: 2012</b>	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied –Part1: General requirements
<b>EN 1041: 2008</b> <b>A1:2013</b>	Terminology, symbols and information provided with medical devices - Information Supplied by the Manufacturer
<b>EN ISO 10993-1: 2009</b> <b>AC:2010</b> <b>ISO 10993-1: 2009</b> <b>Cor1: 2010</b>	Biological evaluation of medical devices – Part 1: Evaluation and testing
<b>EN ISO 10993-2: 2006</b> <b>ISO 10993-2: 2006</b>	Biological evaluation of medical devices – Part 2: Animal welfare requirements
<b>EN ISO 10993-4: 2009</b> <b>ISO 10993-4: 2002</b> <b>Amd 1: 2006</b>	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
<b>EN ISO 10993-5: 2009</b> <b>ISO 10993-5: 2009</b>	Biological evaluation of medical devices – Part 5: Tests for cytotoxicity: <i>in vitro</i> methods
<b>EN ISO 10993-7: 2008</b> <b>AC:2009</b> <b>ISO 10993-7: 2008</b> <b>Cor1:2009</b>	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
<b>EN ISO 10993-10: 2013</b> <b>ISO 10993-10: 2010</b>	Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization
<b>EN ISO 10993-11: 2009</b> <b>ISO 10993-11: 2006</b>	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

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



# 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

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

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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: 2107788CE11

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## 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

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drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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## 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 ASahi 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

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# ADDENDUM

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## 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	

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Managing Director



ing. A.A.M. Laan  
Certification Manager

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# ADDENDUM

Belonging to certificate: 2107788CE11

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## 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

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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 Company registration 09085396



# 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



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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](https://www.bsi-global.com/ClientDirectory).

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](https://www.bsi-global.com/ClientDirectory) or telephone +66(2) 2944889-92.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.



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

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Page: 2 of 2

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