

EC CERTIFICATE

Number: 2107788CE24

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)

Microcatheters for peripheral and coronary vasculatures

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:

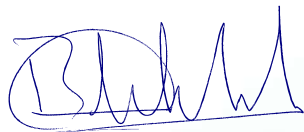
Certification Notice 2107788CN
Addendum, initially dated 26 April 2016

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 May 2024
Issued for the first time: 26 April 2016
Reissued: 1 May 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 Company registration 09085396

ADDENDUM

Belonging to certificate: 2107788CE24

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Microcatheters for peripheral and coronary vasculatures

Issued to:

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

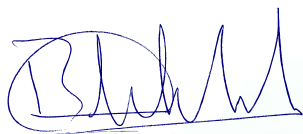
This certificate covers the following product(s):

ASAHI Caravel Microcatheter

Catalogue No.	Product Description
CRV135-19P	2.6Fr, Straight-Tip, 135 cm
CRV150-19P	2.6Fr, Straight-Tip, 150 cm

Initial date: 26 April 2016

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director

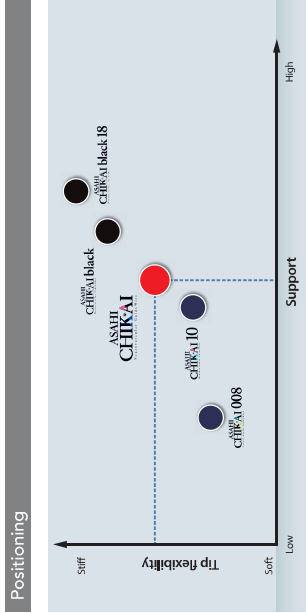


J.A. van Vugt
Certification Manager

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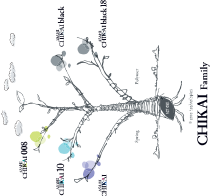
normal vessels / standard cases

tiny vessels / precision cases

tortuous vessels / complex cases

large vessels / high support cases

Specification & ordering information						
Product	Catalog No.	O.D.	Coating	Usable length	Coil length	Tip shape
ASAHI CHIKAI 008	WAN-CH-008-200	0.20 (0.26mm) (0.008") (0.008")	Hydrophilic coating (SIP-COAT™) 180mm	200mm	8mm	Straight
	WAN-CH-16-200	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	200mm	9.5mm	Straight
	WAN-CH-16-300	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	300mm	9.5mm	Straight
ASAHI CHIKAI 10	WAN-CH-10-200	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	200mm	9.5mm	Straight
	WAN-CH-10-300	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	300mm	9.5mm	Straight
	WAN-CH-10-400	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	9.5mm	Straight
ASAHI CHIKAI	WAN-CH-300-200	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	200mm	30mm	Straight
	WAN-CH-300-300	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	300mm	30mm	Straight
	WAN-CH-300-400	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight
ASAHI CHIKAI black	WAN-CH-300-400	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight
	WAN-CH-300-400	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight
	WAN-CH-300-400	0.26mm (0.010mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	30mm	Straight
ASAHI CHIKAI black 18	WAN-CH-18-200	0.45 (0.41mm) (0.018") (0.016mm)	Hydrophilic coating (SIP-COAT™) 170mm	200mm	34mm	Round curve
	WAN-CH-18-300	0.45 (0.41mm) (0.018") (0.016mm)	Hydrophilic coating (SIP-COAT™) 170mm	300mm	34mm	Round curve
	WAN-CH-18-400	0.45 (0.41mm) (0.018") (0.016mm)	Hydrophilic coating (SIP-COAT™) 170mm	400mm	34mm	Round curve



Not all names and figures are available in all countries. Please check carefully with your sales representative.

ASAHI CHIKAI and CHIKAI are trademarks or registered trademarks of ASAHI INTECC CO., LTD. in Japan and other countries.

CE 0344

Manufactured by:

ASAHI INTECC

ASAHI INTECC CO., LTD.

9-1100 Aikawa-cho, Saito, Aichi 486-0271 Japan

Contact phone number: +81-561-466-0101

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

Distributed by:

ASAHI CHIKAI Family ver.1 (MARCH 2012)

ASAHI CHIKAI Family

Neurovascular Guidewire

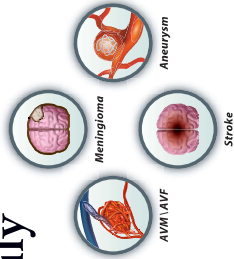
Your dreams. Woven together.

ASAHI INTECC

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.



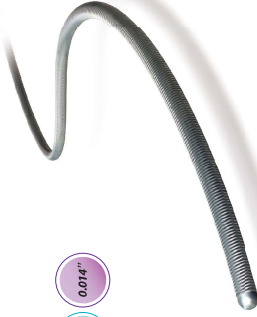
Round curve
#Available for CHIKAI
CHIKAI black and CHIKAI blue is

Angled 90°
#Available for CHIKAI black

ASAHI CHIKAI

Neurovascular GuideWire

ASAHI CHIKAI ASAHI CHIKAI T0 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 T0 (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



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
Latest Revision Date: 2021-07-08

Effective 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
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