EC CERTIFICATE

Number: 2107788CE16

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)

Guidewires for Neuro Vascular procedures

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 28 September 2011

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 October 2022
Issued for the first time: 28 September 2011
Reissued: 1 October 2017

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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

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ADDENDUM

Belonging to certificate: 2107788CE16

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Guidewires for Neuro Vascular procedures

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 Neurovascular Guide Wire

Catalog No.	Brand Name
WAIN-CKI-200	ASAHI CHIKAI 200cm
WAIN-CKI-300	ASAHI CHIKAI 300cm
WAIN-CKI-10-200	ASAHI CHIKAI 10 200cm
WAIN-CKI-10-300	ASAHI CHIKAI 10 300cm
WAIN-CKI-008-200	ASAHI CHIKAI 008
WAIN-CKI-18-200-BS	ASAHI CHIKAI black 18
WAIN-CKI-200-BS	ASAHI CHIKAI black
WAIN-CKI-200-BA	ASAHI CHIKAI black
WAIN-CKI-200-RC	ASAHI CHIKAI
WAIN-CKI-300-RC	ASAHI CHIKAI
AIN-CKI-200-B-SFT	ASAHI CHIKAI black 14 soft tip
AIN-CKI-18-200-SFT	ASAHI CHIKAI black 18 soft tip

Initial date: 28 September 2011
Revision date: 19 March 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

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