EC DESIGN-EXAMINATION CERTIFICATE

Number: 2107788DE14

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

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

For the product

Guidewires for Neuro Vascular procedures

Documents, that form the basis of this certificate:

Certification Notice 2107788CN
CE Marking of Conformity 2107788CE16
Addendum, initially dated 28 September 2011

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
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: 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: 2107788DE14

EC DESIGN-EXAMINATION
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

Initial date: 28 September 2011
Revision date: 1 October 2017

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