

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

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

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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 |
| Astato 30 | PAGH18M071 | ASAHI Peripheral Guide Wire Astato 30 |
| | PAGH18M371 | ASAHI Peripheral Guide Wire Astato 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 |
| Astato XS 20 | PAGH143092 | ASAHI Peripheral Guide Wire Astato XS 20 |
| | PAGH143392 | ASAHI Peripheral Guide Wire Astato XS 20 300cm |
| Treasure Floppy | PAGH18M072 | ASAHI Peripheral Guide Wire Treasure Floppy |
| | PAGH18M372 | ASAHI Peripheral Guide Wire Treasure Floppy 300cm |

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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 PPW14R200S PPW14R300S PPW18R100S PPW18R200S PPW18R300S PPW14R100P PPW14R200P PPW14R300P PPW18R100P PPW18R200P PPW18R300P | ASAHI Peripheral Guide Wire ASahi Gladius |

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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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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

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