

EC CERTIFICATE

Number: 2107788CE10

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)

Sterile MicroCatheters for providing support to facilitate the placement of guide wires in the coronary, abdominal and/or peripheral vasculatures including infusing agent, exchanging one guide wire for another

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 11 November 2008

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: 26 May 2024
Issued for the first time: 11 November 2008
Revised: 26 February 2020
Reissued: 1 December 2019

DEKRA Certification B.V.

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

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ADDENDUM

Belonging to certificate: 2107788CE10

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Sterile MicroCatheters for providing support to facilitate the placement of guide wires in the coronary and/or peripheral vasculatures including infusing agent, exchanging one guide wire for another

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 Corsair

Catalogue code list:
 Model No.

1 2 3 4 5 6 - 7 8 9

Example: CSW105-26N

| No. | Description | |
|-----|-------------------|------------------------------------|
| 1-3 | Type | CSW: "ASAHI Corsair" Microcatheter |
| 4-6 | Shaft length (cm) | 100 - 160 |
| 7-8 | French size | 26: 2.6 Fr |
| 9 | Shape size | N: Normal |

Initial date: 11 November 2008

Revision date: 1 April 2011

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