

EC CERTIFICATE

Number: 2107788CE21

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 infusion of substances and for superselective angiography in peripheral 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 6 October 2014

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 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: 6 October 2022

Issued for the first time: 6 October 2014

Reissued: 6 October 2017

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
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ADDENDUM

Belonging to certificate: 2107788CE21

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Sterile Microcatheters for infusion of substances and for superselective angiography in peripheral 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 Masters PARKWAY Microcatheter	
Catalogue No.	Product Name
WMST105-27HF	ASAHI Masters PARKWAY HF Microcatheter
WMST125-27HF	
WMST150-27HF	
WMST105-18PWSF	ASAHI Masters PARKWAY SOFT Microcatheter
WMST125-18PWSF	
WMST150-18PWSF	
WMST45A-18PWSSF	
WMST45A-18PWSF	
WMST105-27HFK	ASAHI Masters PARKWAY HF KIT Guide Wire Pre-loaded Microcatheter
WMST125-27HFK	
WMST105-27HFKM	
WMST125-27HFKM	

Initial date: 6 October 2014

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



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