EC CERTIFICATE

Number: 2107788CE08

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 diagnostic, embolic and therapeutic agents into the vascular systems and for superselective angiography of the abdominal, peripheral and coronary 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 20 November 2007

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 December 2019
Issued for the first time: 20 November 2007
Reissued: 1 December 2016

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

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ADDENDUM

Belonging to certificate: 2107788CE08

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Sterile MicroCatheters for infusion of diagnostic, embolic and therapeutic agents into the vascular systems and for superselective angiography of the abdominal, peripheral and coronary 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):
- STRIDESMOOTH/Stride
- STRIDESMOOTH+

Catalogue code list:
Model No.

1	2	3	4	5	6	-	7	8	9

Example: STD105-22S

No.	Description	
1-3	Type	**STD**: "STRIDESMOOTH" Microcatheter ("Stride" Microcatheter) **STP**: "STRIDESMOOTH+" Microcatheter
4-6	Shaft length (cm)	100 - 160
7-8	French size	**20**: 2.0 Fr **22**: 2.2 Fr **26**: 2.6 Fr
9	Shape size	**S**: Straight **A**: Angle 45°

Initial date: 20 November 2007
Revision date: 1 April 2011

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

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