EC CERTIFICATE

Number: 2107788CE23

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)

Guide Catheters for Neurovascular procedures

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 5 July 2015

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: 5 July 2023
Issued for the first time: 5 July 2015
Reissued: 5 July 2018

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

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: 2107788CE23

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Guide Catheters for Neurovascular 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 FUBUKI 043 Distal Support System	
Catalogue No.	Product Name
WAIN-FBK-4-120	ASAHI FUBUKI 043 (4.2Fr)
WAIN-FBK-4-125	
WAIN-FBK-4-130	

Initial date: 5 July 2015

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

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: 2107788CE23

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Guide Catheters for Neurovascular procedures

Issued to:

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

ASAHI FUBUKI Neurovascular Guide Catheter	
Catalogue No.	Product Name
WAIN-FBK-6S80	ASAHI FUBUKI 6Fr
WAIN-FBK-6S	
WAIN-FBK-6SL	
WAIN-FBK-6S110	
WAIN-FBK-6A80	
WAIN-FBK-6A	
WAIN-FBK-6AL	
WAIN-FBK-6A110	
WAIN-FBK-6A80H	
WAIN-FBK-6AH	
WAIN-FBK-6ALH	
WAIN-FBK-6A110H	
WAIN-FBK-7S80	ASAHI FUBUKI 7Fr
WAIN-FBK-7S	
WAIN-FBK-7SL	
WAIN-FBK-7S110	
WAIN-FBK-7A80	
WAIN-FBK-7A	
WAIN-FBK-7AL	
WAIN-FBK-7A110	
WAIN-FBK-7A80H	
WAIN-FBK-7AH	
WAIN-FBK-7ALH	
WAIN-FBK-7A110H	
WAIN-FBK-8S80	ASAHI FUBUKI 8Fr
WAIN-FBK-8S	
WAIN-FBK-8SL	
WAIN-FBK-8S110	

Initial date: 5 July 2015

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

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: 2107788CE23

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Guide Catheters for Neurovascular procedures

Issued to:

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

ASAHI FUBUKI Neurovascular Guide Catheter Dilator Kit	
Catalogue No.	Product Name
WAIN-FBK-4SD80	ASAHI FUBUKI Dilator Kit 4Fr
WAIN-FBK-4SD	
WAIN-FBK-4SDL	
WAIN-FBK-4SD110	
WAIN-FBK-4AD80	
WAIN-FBK-4AD	
WAIN-FBK-4ADL	
WAIN-FBK-4AD110	
WAIN-FBK-4AD80H	
WAIN-FBK-4ADH	
WAIN-FBK-4ADLH	
WAIN-FBK-4AD110H	
WAIN-FBK-5SD80	ASAHI FUBUKI Dilator Kit 5Fr
WAIN-FBK-5SD	
WAIN-FBK-5SDL	
WAIN-FBK-5SD110	
WAIN-FBK-5AD80	
WAIN-FBK-5AD	
WAIN-FBK-5ADL	
WAIN-FBK-5AD110	
WAIN-FBK-5AD80H	
WAIN-FBK-5ADH	
WAIN-FBK-5ADLH	
WAIN-FBK-5AD110H	
WAIN-FBK-6SD80	ASAHI FUBUKI Dilator Kit 6Fr
WAIN-FBK-6SD	
WAIN-FBK-6SDL	
WAIN-FBK-6SD110	

Initial date: 5 July 2015
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

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