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

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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

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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

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2107788DE14

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

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

For the product

Guidewires for Neuro Vascular procedures

Documents, that form the basis of this certificate:

Certification Notice 2107788CN
CE Marking of Conformity 2107788CE16
Addendum, initially dated 28 September 2011

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 October 2022
Issued for the first time: 28 September 2011
Reissued: 1 October 2017

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: 2107788DE14

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Guidewires for Neuro Vascular 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 Neurovascular Guide Wire

Catalog No.	Brand Name
WAIN-CKI-200	ASAHI CHIKAI 200cm
WAIN-CKI-300	ASAHI CHIKAI 300cm
WAIN-CKI-10-200	ASAHI CHIKAI 10 200cm
WAIN-CKI-10-300	ASAHI CHIKAI 10 300cm
WAIN-CKI-008-200	ASAHI CHIKAI 008
WAIN-CKI-18-200-BS	ASAHI CHIKAI black 18
WAIN-CKI-200-BS	ASAHI CHIKAI black
WAIN-CKI-200-BA	ASAHI CHIKAI black
WAIN-CKI-200-RC	ASAHI CHIKAI
WAIN-CKI-300-RC	ASAHI CHIKAI

Initial date: 28 September 2011
Revision date: 1 October 2017

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

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2107788DE19

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

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

For the product

Guide Catheters for Neurovascular procedures

Documents, that form the basis of this certificate:

Certification Notice 2107788CN,
Addendum, initially dated 5 July 2015

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and 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: 2107788DE19

EC DESIGN-EXAMINATION
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
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ADDENDUM

Belonging to certificate: 2107788DE19

EC DESIGN-EXAMINATION
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

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ADDENDUM

Belonging to certificate: 2107788DE19

EC DESIGN-EXAMINATION
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

Jan. 30. 2024

DECLARATION OF CONFORMITY (MDD)

1. Name and address of the firm: ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

We declare under our sole responsibility that

the medical device: (Name) ASAHI Neurovascular Guide Wire

(Model)

WAIN-CKI-008-200	ASAHI CHIKAI 008
WAIN-CKI-200-BS	ASAHI CHIKAI black
WAIN-CKI-200-BA	ASAHI CHIKAI black
WAIN-CKI-18-200-BS	ASAHI CHIKAI black 18

(Serial of Lot No.)
From 141106A39A to

Name, type or model, batch or serial number, possibly source and number of items

of Class: III

According to Rule 7 in annex IX of directive 93/42/EEC

meets all the provisions of the directive 93/42/EEC which apply it.

2. EC Design Examination Certificate No.: 2107788DE14
Issued by: DEKRA Certification B. V. (Notified under No. 0344) Arnhem, The Netherlands

3. CE Marking of Conformity Certificate No.: 2107788CE16
Issued by: DEKRA Certification B. V. (Notified under No. 0344) Arnhem, The Netherlands

4. Manufacturing Facility: ASAHI INTECC HANOI CO., LTD. THANG LONG Industrial Park Dong Anh District Hanoi Vietnam

5. Authorized representative in EU: Emergo Europe Prinsessegracht 20, 2514 AP The Hague, The Netherlands

6. Applied harmonized standards, national standards or other normative documents: Refer to Table 1 and Table 2

7. Conformity assessment procedure: Based on Medical Devices Directive 93/42/EEC Annex II 3 and 4

8. Signature of Manufacturer

3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN
January 18, 2021
Place, Date

Yasuyuki Kawahara
General Manager
Quality Assurance Division
ASAHI INTECC CO., LTD.

Table 1: Applied harmonized standards (QA-Related Standards)

Standard Reference	Title
EN ISO 13485:2016 A: 2016 ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EC Directive 93/42/EEC:1993 /Amd1:1998 /Amd2:2000 /Amd3:2002 /Amd4:2003 /Amd5:2007	Medical Devices Directive (2007)

Table 2: Applied harmonized standards (Product related standards)

Standard Reference	Title
EN 556-1:2001 AC: 2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 15223-1: 2016 C1:2017/C2:2017 ISO 15223-1: 2016 C1:2016/C2:2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements
EN 1041:2008 A:2013	Information Supplied by the Manufacturer of Medical Devices
EN 62366-1:2015 C:2016	Medical devices – Part 1: Application of usability engineering to medical devices
EN ISO 10993-1: 2009 AC:2010 ISO 10993-1: 2009 AC:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-2: 2006 ISO 10993-2: 2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements
EN ISO 10993-4: 2017 ISO 10993-4: 2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5: 2009 ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for *in vitro* Cytotoxicity
EN ISO 10993-7: 2008 AC:2009 ISO 10993-7: 2008 C1:2009/A1:2019	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10: 2013 ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11: 2018 ISO 10993-11: 2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12: 2012 ISO 10993-12: 2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

Standard Reference	Title
EN ISO 11070: 2014 A1:2018 **ISO 11070: 2014 A1:2018**	Sterile single-use intravascular introducers, dilators and guidewires
EN ISO 11135: 2014 A1:2019 **ISO 11135: 2014 AMENDMENT1:2018**	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-1: 2017 **ISO 11138-1: 2017**	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2: 2017 **ISO 11138-2: 2017**	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11138-7: 2019 **ISO 11138-7: 2019**	Sterilization of Health Care Products - Biological Indicators – Part 7: Guidance for the Selection, Use and Interpretation of Results
EN ISO 11607-1: 2017 **ISO 11607-1: 2006 A:2014**	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2: 2017 **ISO 11607-2: 2006 A:2014**	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1: 2018 C:2018 **ISO 11737-1: 2018**	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2: 2009 **ISO 11737-2: 2009**	Sterilization of health care products – Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14155: 2011 AC: 2011 **ISO 14155: 2011 C: 2011**	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 14644-1: 2015 **ISO 14644-1: 2015**	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness by particle concentration
EN ISO 14644-2: 2015 **ISO 14644-2: 2015**	Cleanrooms and Associated Controlled Environments - Part 2: Monitoring to Provide Evidence of Cleanroom Performance Related to Air Cleanliness by Particle Concentration
EN ISO 14644-3: 2019 **ISO 14644-3: 2019**	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14698-1: 2003 C:2003 **ISO 14698-1: 2003**	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
EN ISO 14698-2: 2003 AC: 2006 **ISO 14698-2: 2003 C: 2004**	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
EN ISO 14971: 2019 **ISO 14971: 2019**	Medical devices – Application of risk management to medical devices
MEDDEV. 2.12-1: 2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
MEDDEV.2.7/1: 2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
MEDDEV.2.12-2:2012	POST MARKET CLINICAL FOLLOW-UP STUDIES

Addendum to the original Declaration of Conformity (MDD)

The following changes have been made on the respective dates:

Date of Change	Descriptions	Corresponding Version
June 25, 2021	-The applicable standards were updated to the following: EN ISO 11607-1: 2020 ISO 11607-1: 2019 ISO 11607-2: 2019	AMM-CD001 Ver.10
October 22, 2021	-The title of the company representative was changed from "General Manager" to "Person responsible for regulatory compliance." -ISO 10993-18:2020 and EN ISO 10993-18:2020 were added to Table 2. -The applicable standards were updated to the following: EN ISO 10993-1:2020 ISO 10993-1: 2018 EN ISO 11737-2: 2020 ISO 11737-2: 2019 EN 62366-1:2015 /A1:2020	AMM-CD001 Ver.11
March 8, 2022	-The applicable standards were updated to the following: EN ISO 10993-12: 2021 ISO 10993-12: 2021 EN ISO 11737-1: 2018 A:2021 ISO 11737-1: 2018 A:2021	AMM-CD001 Ver.12
June 9, 2022	-The applicable standards were updated to the following: EN ISO 10993-7: 2008 (+A1:2022) EN ISO 14971: 2019 (A11:2021)	AMM-CD001 Ver.13
September 14, 2022	-The applicable standards were updated to the following: ISO 10993-10: 2021 ISO10993-18:2020 A1:2021	AMM-CD001 Ver.14
June 1, 2023	- The applicable standards were updated to the following due to the wrong description: EN ISO 10993-1: 2009 AC: 2010 ISO 10993-1: 2009 Cor1: 2010 EN ISO 10993-7: 2008 AC:2009 EN ISO 10993-18: 2009 ISO 10993-18: 2005 EN ISO 11607-1: 2017 ISO 11607-1: 2006 Amd1: 2014 ISO 11607-2: 2006 Amd1: 2014	AMM-CD001 Ver.15

Addendum to the original Declaration of Conformity (MDD)

<table>
<tr><th>Date of Change</th><th>Descriptions</th><th>Corresponding Version</th></tr>
<tr><td></td><td>-As of January 31, 2023, the address of our EU Authorized Representative as listed on the original DoC has been changed.

<table><tr><td>Name of company</td><td>Emergo Europe B.V.</td></tr><tr><td>Old Address</td><td>Prinsessegracht 20, 2514 AP The Hague, The Netherlands</td></tr><tr><td>New Address</td><td>Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands</td></tr></table></td><td></td></tr>
<tr><td>January 30, 2024</td><td>-The applicable standards were updated to the following:
EN ISO 10993-2:2022
ISO 10993-2: 2022
EN ISO 10993-10:2023

-ISO 10993-23:2021 and EN ISO 10993-23:2021 were added to Table 2.</td><td>NA</td></tr>
</table>

Aichi, Japan, January 30, 2024

Place and date of issue

Yasuyuki Kawahara
Person responsible for regulatory compliance
ASAHI INTECC CO., LTD.

DECLARATION OF CONFORMITY (MDD)

1. Name and address of the firm: ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

We declare under our sole responsibility that

the medical device: (Name) ASAHI FUBUKI 043 Distal Support System
ASAHI FUBUKI Neurovascular Guide Catheter
ASAHI FUBUKI Neurovascular Guide Catheter Dilator Kit
(Model)
Refer to Table 1~3
(Serial of Lot No.)
From 151001C011 to
Name, type or model, batch or serial number, possibly source and number of items

of Class: III
According to Rule 7 in annex IX of directive 93/42/EEC

meets all the provisions of the directive 93/42/EEC which apply it.

2. EC Design Examination Certificate No.: 2107788DE19
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

3. CE Marking of Conformity Certificate No.: 2107788CE23
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

4. Manufacturing Facility: ASAHI INTECC CO., LTD. Medical Division
3-100, Akatsuki-cho, Seto, Aichi 489-0071 JAPAN
ASAHI INTECC (THAILAND) CO., LTD.
158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi
Amphur Muang, Pathumthani 12000, Thailand

5. Authorized representative in EU: Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands

6. Applied harmonized standards, national standards or other normative documents: Refer to Table 4 and Table 5

7. Conformity assessment procedure: Based on Medical Devices Directive 93/42/EEC Annex II 3 and 4

3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

June 11, 2020
Place, Date

Yasuyuki Kawahara,
General Manager
Quality Assurance Division
ASAHI INTECC CO., LTD.

Table 1. Catalog Number of ASAHI FUBUKI 043 Distal Support System

Product	Catalog No.	Tip Shape	Distal	Catheter Effective Length
ASAHI FUBUKI 043 (4.2Fr)	WAIN-FBK-4-120	STRAIGHT	—	120cm
	WAIN-FBK-4-125			125cm
	WAIN-FBK-4-130			130cm

Table 2. Catalog Number of ASAHI FUBUKI Neurovascular Guide Catheter

Product	Catalog No.	Tip Shape	Distal	Catheter Effective Length
ASAHI FUBUKI 6Fr	WAIN-FBK-6S80	STRAIGHT	—	80cm
	WAIN-FBK-6S			90cm
	WAIN-FBK-6SL			100cm
	WAIN-FBK-6S110			110cm
	WAIN-FBK-6A80	ANGLED		80cm
	WAIN-FBK-6A			90cm
	WAIN-FBK-6AL			100cm
	WAIN-FBK-6A110			110cm
	WAIN-FBK-6A80H	ANGLED	STIFF	80cm
	WAIN-FBK-6AH			90cm
	WAIN-FBK-6ALH			100cm
	WAIN-FBK-6A110H			110cm
ASAHI FUBUKI 7Fr	WAIN-FBK-7S80	STRAIGHT	—	80cm
	WAIN-FBK-7S			90cm
	WAIN-FBK-7SL			100cm
	WAIN-FBK-7S110			110cm
	WAIN-FBK-7A80	ANGLED		80cm
	WAIN-FBK-7A			90cm
	WAIN-FBK-7AL			100cm
	WAIN-FBK-7A110			110cm
	WAIN-FBK-7A80H	ANGLED	STIFF	80cm
	WAIN-FBK-7AH			90cm
	WAIN-FBK-7ALH			100cm
	WAIN-FBK-7A110H			110cm
ASAHI FUBUKI 8Fr	WAIN-FBK-8S80	STRAIGHT	-	80cm
	WAIN-FBK-8S			90cm
	WAIN-FBK-8SL			100cm
	WAIN-FBK-8S110			110cm

Table 3. Catalog Number of ASAHI FUBUKI Neurovascular Guide Catheter Dilator Kit

Product	Catalog No.	Tip Shape	Distal	Catheter Effective Length
ASAHI FUBUKI Dilator Kit 4Fr	WAIN-FBK-4SD80	STRAIGHT	—	80cm
	WAIN-FBK-4SD			90cm
	WAIN-FBK-4SDL			100cm
	WAIN-FBK-4SD110			110cm
	WAIN-FBK-4AD80	ANGLED		80cm
	WAIN-FBK-4AD			90cm
	WAIN-FBK-4ADL			100cm
	WAIN-FBK-4AD110			110cm
	WAIN-FBK-4AD80H	ANGLED	STIFF	80cm
	WAIN-FBK-4ADH			90cm
	WAIN-FBK-4ADLH			100cm
	WAIN-FBK-4AD110H			110cm
ASAHI FUBUKI Dilator Kit 5Fr	WAIN-FBK-5SD80	STRAIGHT	—	80cm
	WAIN-FBK-5SD			90cm
	WAIN-FBK-5SDL			100cm
	WAIN-FBK-5SD110			110cm
	WAIN-FBK-5AD80	ANGLED		80cm
	WAIN-FBK-5AD			90cm
	WAIN-FBK-5ADL			100cm
	WAIN-FBK-5AD110			110cm
	WAIN-FBK-5AD80H	ANGLED	STIFF	80cm
	WAIN-FBK-5ADH			90cm
	WAIN-FBK-5ADLH			100cm
	WAIN-FBK-5AD110H			110cm
ASAHI FUBUKI Dilator Kit 6Fr	WAIN-FBK-6SD80	STRAIGHT	-	80cm
	WAIN-FBK-6SD			90cm
	WAIN-FBK-6SDL			100cm
	WAIN-FBK-6SD110			110cm

Table 4: Applied harmonized standards (QA-Related Standards)

Standard Reference	Title
EN ISO 13485:2016 **A: 2016** **ISO 13485:2016**	Medical devices -- Quality management systems -- Requirements for regulatory purposes
93/42/EEC:1993 **Amd1:1998** **Amd2:2000** **Amd3:2002** **Amd4:2003** **Amd5:2007**	Medical Devices Directive (2007)

Table 5: Applied harmonized standards (Product related standards）

Standard Reference 規格略号･番号	Title タイトル
EN 556-1:2001 **AC: 2006**	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile"- Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 15223-1: 2016 **C1 2017/C2 2017** **ISO 15223-1: 2016** **C1 2016/C2 2017**	Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied –Part 1: General requirements
EN 1041:2008 **A: 2013**	Information Supplied by the Manufacturer of Medical Devices
EN ISO 10555-1:2013 **C: 2013/A: 2017** **ISO 10555-1:2013** **A: 2017**	Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements
EN 13868: 2002	Catheters - Test methods for Kinking of Single Lumen Catheters and Medical Tubing
EN ISO 10993-1:2009 **AC: 2010** **ISO 10993-1: 2009** **AC: 2010**	Biological evaluation of medical devices – Part 1: Evaluation and Testing within a risk management process
EN ISO 10993-2: 2006 **ISO 10993-2: 2006**	Biological evaluation of medical devices - Part 2: Animal welfare requirements
EN ISO 10993-4: 2017 **ISO 10993-4: 2017**	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood

Standard Reference 規格略号･番号	Title タイトル
EN ISO 10993-5: 2009 **ISO 10993-5: 2009**	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7: 2008 **AC 2009** **ISO 10993-7: 2008** **C1: 2009 A1:2019**	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10: 2013 **ISO 10993-10: 2010**	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11: 2018 **ISO 10993-11: 2017**	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12: 2012 **ISO 10993-12: 2012**	Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials
EN ISO 11135: 2014 **A1:2019** **ISO 11135: 2014** **A1:2018**	Sterilization of health-care products -Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-1: 2017 **ISO 11138-1: 2017**	Sterilization of health care products - Biological indicators - Part 1: General requirements
EN ISO 11138-2: 2017 **ISO 11138-2: 2017**	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11138-7:2019 **ISO 11138-7:2019**	Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results
EN ISO 11607-1: 2017 **ISO 11607-1: 2006** **A: 2014**	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2: 2017 **ISO 11607-2: 2006** **A: 2014**	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 14698-1: 2003/ **C: 2003** **ISO 14698-1: 2003**	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
EN ISO 14698-2: 2003 **AC: 2006** **ISO 14698-2: 2003** **C1: 2004**	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
EN ISO 11737-1: 2018 **C: 2018** **ISO 11737-1: 2018**	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products

Standard Reference 規格略号･番号	Title タイトル
EN ISO 11737-2: 2009 **ISO 11737-2: 2009**	Sterilization of Medical Devices – Microbiological Methods - Part 2: Tests of Sterility Performed in the definition, validation and maintenance of a sterilization process
EN ISO 14155: 2011 **AC: 2011** **ISO 14155: 2011** **C: 2011**	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 14644-1: 2015 **ISO 14644-1: 2015**	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2: 2015 **ISO 14644-2: 2015**	Cleanrooms and associated controlled environments - Part 2: Monitoring to Provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN ISO 14644-3: 2005 **ISO 14644-3: 2005**	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14971: 2012 **ISO 14971: 2007**	Medical devices – Application of risk management to medical devices
EN 62366-1:2015 **C: 2016**	Medical devices – Application of usability engineering to medical devices
EN 20594-1:1993 **AC 1996** **A1 1997** **ISO 594-1:1986**	Conical Fittings with a 6%(Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1: General Requirements
EN 1707:1996 **ISO 594-2:1998**	Conical Fittings with a 6%(Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings
EN ISO 80369-1:2018 **ISO 80369-1:2018**	Small-bore connectors for liquids and gases in healthcare applications- Part 1: General requirements
EN ISO 80369-7:2017 **C:2017** **ISO 80369-7:2016**	Small-bore connectors for liquids and gases in healthcare applications- Part 7: Connectors for intravascular or hypodermic applications
EN ISO 11070:2014 **A1: 2018** **ISO 11070:2014** **A1: 2018**	Sterile single - use intravascular introducers, dilators and guidewires
MEDDEV. 2.12-1: 2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM

Standard Reference 規格略号・番号	Title タイトル
MEDDEV.2.12-2: 2012	POST MARKET CLINICAL FOLLOW-UP STUDIES
MEDDEV. 2.7/1: 2016	CLINICAL EVALUATION : A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

Jan. 30, 2024

DECLARATION OF CONFORMITY (MDD)

1. Name and address of the firm: ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

We declare under our sole responsibility that

the medical device: (Name) ASAHI Neurovascular Guide Wire
(Model) WAIN-CKI-200-RC ASAHI CHIKAI 200cm (Round curve type)
WAIN-CKI-300-RC ASAHI CHIKAI 300cm (Round curve type)
(Serial of Lot No.)
From 161007A01A / WAIN-CKI-200-RC) to
Name, type or model, batch or serial number, possibly source and number of items

of Class: III
According to Rule 7 in annex IX of directive 93/42/EEC

meets all the provisions of the directive 93/42/EEC which apply it.

2. EC Design Examination Certificate No.: 2107788DE14
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

3. CE Marking of Conformity Certificate No.: 2107788CE16
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

4. Manufacturing Facility: ASAHI INTECC HANOI CO., LTD.
THANG LONG Industrial Park Dong Anh District Hanoi Vietnam

5. Authorized representative in EU: Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands

6. Applied harmonized standards, national standards or other normative documents: Refer to Table 1 and Table 2

7. Conformity assessment procedure: Based on Medical Devices Directive 93/42/EEC Annex II 3 and 4

8. Signature of Manufacturer

3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN
January 18, 2021
Place, Date

Yasuyuki Kawahara,
General Manager
Quality Assurance Division
ASAHI INTECC CO., LTD.

Table 1: Applied harmonized standards (QA-Related Standards)

Standard Reference	Title
EN ISO 13485:2016 A: 2016 ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EC Directive 93/42/EEC:1993 /Amd1:1998 /Amd2:2000 /Amd3:2002 /Amd4:2003 /Amd5:2007	Medical Devices Directive (2007)

Table 2: Applied harmonized standards (Product related standards)

Standard Reference	Title
EN 556-1:2001 AC: 2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 15223-1: 2016 C1:2017/C2:2017 ISO 15223-1: 2016 C1:2016/C2:2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008 A:2013	Information Supplied by the Manufacturer of Medical Devices
EN 62366-1:2015 C:2016	Medical devices – Part 1: Application of usability engineering to medical devices
EN ISO 10993-1: 2009 AC:2010 ISO 10993-1: 2009 AC:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-2: 2006 ISO 10993-2: 2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements
EN ISO 10993-4: 2017 ISO 10993-4: 2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5: 2009 ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for in Vitro Cytotoxicity
EN ISO 10993-7: 2008 AC:2009 ISO 10993-7: 2008 C1:2009/A1:2019	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10: 2013 ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11: 2018 ISO 10993-11: 2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12: 2012 ISO 10993-12: 2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

Standard Reference	Title
EN ISO 11070: 2014 A1:2018 **ISO 11070: 2014 A1:2018**	Sterile single-use intravascular introducers, dilators and guidewires
EN ISO 11135: 2014 A1:2019 **ISO 11135: 2014 AMENDMENT1:2018**	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-1: 2017 **ISO 11138-1: 2017**	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2: 2017 **ISO 11138-2: 2017**	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11138-7: 2019 **ISO 11138-7: 2019**	Sterilization of Health Care Products - Biological Indicators – Part 7: Guidance for the Selection, Use and Interpretation of Results
EN ISO 11607-1: 2017 **ISO 11607-1: 2006 A:2014**	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2: 2017 **ISO 11607-2: 2006 A:2014**	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1: 2018 C:2018 **ISO 11737-1: 2018**	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2: 2009 **ISO 11737-2: 2009**	Sterilization of health care products – Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14155: 2011 AC: 2011 **ISO 14155: 2011 Cor1: 2011**	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 14644-1: 2015 **ISO 14644-1: 2015**	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness by Particle Concentration
EN ISO 14644-2: 2015 **ISO 14644-2: 2015**	Cleanrooms and Associated Controlled Environments - Part 2: Monitoring to Provide Evidence of Cleanroom Performance Related to Air Cleanliness by Particle Concentration
EN ISO 14644-3: 2019 **ISO 14644-3: 2019**	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14698-1: 2003 C:2003 **ISO 14698-1: 2003**	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
EN ISO 14698-2: 2003 AC: 2006 **ISO 14698-2: 2003 C: 2004**	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
EN ISO 14971: 2019 **ISO 14971: 2019**	Medical devices – Application of risk management to medical devices
MEDDEV. 2.12-1: 2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
MEDDEV.2.7/1: 2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
MEDDEV.2.12-2:2012	POST MARKET CLINICAL FOLLOW-UP STUDIES

Addendum to the original Declaration of Conformity (MDD)

The following changes have been made on the respective dates:

Date of Change	Descriptions	Corresponding Version
June 25, 2021	-The applicable standards were updated to the following: EN ISO 11607-1: 2020 ISO 11607-1: 2019 ISO 11607-2: 2019	AMM-CD034 Ver.7
October 22, 2021	-The title of the company representative was changed from "General Manager" to "Person responsible for regulatory compliance." -ISO 10993-18:2020 and EN ISO 10993-18:2020 were added to Table 2. -The applicable standards were updated to the following: EN ISO 10993-1:2020 ISO 10993-1: 2018 EN ISO 11737-2: 2020 ISO 11737-2: 2019 EN 62366-1:2015 /A1:2020	AMM-CD034 Ver.8
June 9, 2022	-The applicable standards were updated to the following: EN ISO 10993-7: 2008 A1:2022 EN ISO 10993-12: 2021 ISO 10993-12: 2021 EN ISO 11737-1: 2018 A:2021 ISO 11737-1: 2018 A:2021 EN ISO 14971: 2019 A11:2021	AMM-CD034 Ver.9
September 14, 2022	-The applicable standards were updated to the following: ISO 10993-10: 2021 ISO 10993-18:2020 A1:2021	AMM-CD034 Ver.10
June 1, 2023	-The applicable standards were updated to the following due to the wrong description: EN ISO 10993-1: 2009 AC: 2010 ISO 10993-1: 2009 Cor1: 2010 EN ISO 10993-7: 2008 AC:2009 EN ISO 10993-18: 2009 ISO 10993-18: 2005 EN ISO 11607-1: 2017 ISO 11607-1: 2006 Amd1: 2014 ISO 11607-2: 2006 Amd1: 2014	AMM-CD034 Ver.11

Addendum to the original Declaration of Conformity (MDD)

<table>
<tr><th>Date of Change</th><th>Descriptions</th><th>Corresponding Version</th></tr>
<tr><td></td><td>-As of January 31, 2023, the address of our EU Authorized Representative as listed on the original DoC has been changed.
<table>
<tr><td>Name of company</td><td>Emergo Europe B.V.</td></tr>
<tr><td>Old Address</td><td>Prinsessegracht 20, 2514 AP The Hague, The Netherlands</td></tr>
<tr><td>New Address</td><td>Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands</td></tr>
</table></td><td></td></tr>
<tr><td>January 30, 2024</td><td>-The applicable standards were updated to the following:
EN ISO 10993-2: 2022
ISO 10993-2: 2022
EN ISO 10993-10:2023

-ISO 10993-23:2021 and EN ISO 10993-23:2021 were added to Table 2.</td><td>NA</td></tr>
</table>

Aichi, Japan, January 30, 2024

Place and date of issue

Yasuyuki Kawahara
Person responsible for regulatory compliance
ASAHI INTECC CO., LTD.

Jan. 30, 2024

DECLARATION OF CONFORMITY (MDD)

1. Name and address of the firm: ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

We declare under our sole responsibility that

the medical device: (Name) ASAHI Neurovascular Guide Wire
(Model)
AIN-CKI-18-200-SFT ASAHI CHIKAI black 18 soft tip
AIN-CKI-200-B-SFT ASAHI CHIKAI black 14 soft tip
(Serial of Lot No./ Catalog code)
From 180605A33A / AIN-CKI-18-200-SFT to
Name, type or model, batch or serial number, possibly source and number of items

of Class: III
According to Rule 7 in annex IX of directive 93/42/EEC

meets all the provisions of the directive 93/42/EEC which apply it.

2. EC Design Examination Certificate No.: 2107788DE14
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

3. CE Marking of Conformity Certificate No.: 2107788CE16
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

4. Manufacturing Facility: ASAHI INTECC HANOI CO., LTD.
THANG LONG Industrial Park Dong Anh District Hanoi Vietnam

5. Authorized representative in EU: Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands

6. Applied harmonized standards, national standards or other normative documents: Refer to Table 1 and Table 2

7. Conformity assessment procedure: Based on Medical Devices Directive 93/42/EEC Annex II 3 and 4

8. Signature of Manufacturer

3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN
January 18, 2021
Place, Date

Yasuyuki Kawahara,
General Manager
Quality Assurance Division
ASAHI INTECC CO., LTD.

Table 1: Applied harmonized standards (QA-Related Standards)

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EC Directive 93/42/EEC:1993 /Amd1:1998 /Amd2:2000 /Amd3:2002 /Amd4:2003 /Amd5:2007	Medical Devices Directive (2007)

Table 2: Applied harmonized standards (Product related standards)

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EN ISO 15223-1: 2016 C1:2017/C2:2017 ISO 15223-1: 2016 C1:2016/C2:2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements
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EN 62366-1:2015 C:2016	Medical devices – Part1: Application of usability engineering to medical devices
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EN ISO 10993-2: 2006 ISO 10993-2: 2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements
EN ISO 10993-4: 2017 ISO 10993-4: 2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5: 2009 ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for *in vitro* Cytotoxicity
EN ISO 10993-7: 2008 AC:2009 ISO 10993-7: 2008 C1:2009/A1:2019	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10: 2013 ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11: 2018 ISO 10993-11: 2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12: 2012 ISO 10993-12: 2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

Standard Reference	Title
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EN ISO 11135: 2014 A1:2019 **ISO 11135: 2014 AMENDMENT1:2018**	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-1: 2017 **ISO 11138-1: 2017**	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2: 2017 **ISO 11138-2: 2017**	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11138-7: 2019 **ISO 11138-7: 2019**	Sterilization of Health Care Products - Biological Indicators – Part 7: Guidance for the Selection, Use and Interpretation of Results
EN ISO 11607-1: 2017 **ISO 11607-1: 2006 A:2014**	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2: 2017 **ISO 11607-2: 2006 A:2014**	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1: 2018 C:2018 **ISO 11737-1: 2018**	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2: 2009 **ISO 11737-2: 2009**	Sterilization of health care products – Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14155: 2011 AC: 2011 **ISO 14155: 2011 C: 2011**	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 14644-1: 2015 **ISO 14644-1: 2015**	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness by particle concentration
EN ISO 14644-2: 2015 **ISO 14644-2: 2015**	Cleanrooms and Associated Controlled Environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN ISO 14644-3: 2019 **ISO 14644-3: 2019**	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14698-1: 2003 C:2003 **ISO 14698-1: 2003**	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
EN ISO 14698-2: 2003 AC: 2006 **ISO 14698-2: 2003 C: 2004**	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
EN ISO 14971: 2019 **ISO 14971: 2019**	Medical devices – Application of risk management to medical devices
MEDDEV. 2.12-1: 2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
MEDDEV.2.7/1: 2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
MEDDEV.2.12-2:2012	POST MARKET CLINICAL FOLLOW-UP STUDIES

Addendum to the original Declaration of Conformity (MDD)

The following changes have been made on the respective dates:

Date of Change	Descriptions	Corresponding Version
June 25, 2021	-The applicable standards were updated to the following: EN ISO 11607-1: 2020 ISO 11607-1: 2019 ISO 11607-2: 2019	AMM-CD043 Ver.6
October 22, 2021	-The title of the company representative was changed from "General Manager" to "Person responsible for regulatory compliance." -ISO 10993-18:2020 and EN ISO 10993-18:2020 were added to Table 2. -The applicable standards were updated to the following: EN ISO 10993-1:2020 ISO 10993-1: 2018 EN ISO 11737-2: 2020 ISO 11737-2: 2019 EN 62366-1:2015 A1:2020	AMM-CD043 Ver.7
March 8, 2022	-The applicable standards were updated to the following: EN ISO 10993-12: 2021 ISO 10993-12: 2021 EN ISO 11737-1: 2018 A:2021 ISO 11737-1: 2018 A:2021	AMM-CD043 Ver.8
June 9, 2022	-The applicable standards were updated to the following: EN ISO 10993-7: 2008 (+A1:2022) EN ISO 14971: 2019 A11:2021	AMM-CD043 Ver.9
September 14, 2022	-The applicable standards were updated to the following: ISO 10993-10: 2021 ISO10993-18:2020 A1:2021	AMM-CD043 Ver.10
June 1, 2023	-The applicable standards were updated to the following due to the wrong description: EN ISO 10993-1: 2009 AC: 2010 ISO 10993-1: 2009 Cor1: 2010 EN ISO 10993-7: 2008 AC:2009 EN ISO 10993-18: 2009 ISO 10993-18: 2005 EN ISO 11607-1: 2017 ISO 11607-1: 2006 Amd1: 2014 ISO 11607-2: 2006 Amd1: 2014	AMM-CD043 Ver.11

Addendum to the original Declaration of Conformity (MDD)

<table>
<tr><th>Date of Change</th><th>Descriptions</th><th>Corresponding Version</th></tr>
<tr><td></td><td>-As of January 31, 2023, the address of our EU Authorized Representative as listed on the original DoC has been changed.
<table>
<tr><td>Name of company</td><td>Emergo Europe B.V.</td></tr>
<tr><td>Old Address</td><td>Prinsessegracht 20, 2514 AP The Hague, The Netherlands</td></tr>
<tr><td>New Address</td><td>Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands</td></tr>
</table></td><td></td></tr>
<tr><td>January 30, 2024</td><td>-The applicable standards were updated to the following:
EN ISO 10993-2: 2022
ISO 10993-2: 2022
EN ISO 10993-10: 2023

-ISO 10993-23:2021 and EN ISO 10993-23:2021 were added to Table 2.</td><td>NA</td></tr>
</table>

Aichi, Japan, January 30, 2024

Place and date of issue

Yasuyuki Kawahara
Person responsible for regulatory compliance
ASAHI INTECC CO., LTD.

Manufacturer's Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	ASAHI INTECC CO., LTD.
Manufacturer address and contact details	3-100 Akatsuki-cho, Seto Aichi 489-0071 Japan
Single Registration Number (SRN)	JP-MF-000010199

Authorised Representative name	Emergo Europe B.V.
Authorised Representative address and contact details	Westervoortsedijk 60 6827 AT Arnhem The Netherlands
Single Registration Number (SRN)	NL-AR-000000116

Notified body name	DEKRA Certification B.V.
Notified body number	0344
Directive Certificate number(s) to which this confirmation is made	2107788CE16/2107788DE14
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	01 October 2022
End date of extended validity/transition period	31 December 2027

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached list and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached list

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

  ☑ Expired *before* 20 March 2023:

  ☑ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  ☐ Expired/expires *after* 20 March 2023:

  ☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached list or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached list**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

ASAHI INTECC CO., LTD.

Aichi, Japan, 17 August 2023

Place and date of issue

Yasuyuki Kawahara
Person responsible for regulatory compliance

List of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device	
ASAHI Neurovascular Guide Wire ASAHI CHIKAI	WAIN-CKI-200
ASAHI Neurovascular Guide Wire ASAHI CHIKAI	WAIN-CKI-300
ASAHI Neurovascular Guide Wire ASAHI CHIKAI	WAIN-CKI-200-RC
ASAHI Neurovascular Guide Wire ASAHI CHIKAI	WAIN-CKI-300-RC
ASAHI Neurovascular Guide Wire ASAHI CHIKAI 10	WAIN-CKI-10-200
ASAHI Neurovascular Guide Wire ASAHI CHIKAI 10	WAIN-CKI-10-300
ASAHI Neurovascular Guide Wire ASAHI CHIKAI 008	WAIN-CKI-008-200
ASAHI Neurovascular Guide Wire ASAHI CHIKAI black 18	WAIN-CKI-18-200-BS
ASAHI Neurovascular Guide Wire ASAHI CHIKAI black	WAIN-CKI-200-BS
ASAHI Neurovascular Guide Wire ASAHI CHIKAI black	WAIN-CKI-200-BA
ASAHI Neurovascular Guide Wire ASAHI CHIKAI black 14 soft tip	AIN-CKI-200-B-SFT
ASAHI Neurovascular Guide Wire ASAHI CHIKAI black 18 soft tip	AIN-CKI-18-200-SFT
ASAHI Neurovascular Guide Wire ASAHI CHIKAI X010	AIN-CKX-10-200-R

Revision History

Ver.	Date	Description
1	8 June 2023	Newly established
2	17 August 2023	Change of end date of extended validity/transition period because it was confirmed that this product met all the requirements for the extension until 31 December 2027.

Manufacturer's Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	ASAHI INTECC CO., LTD.
Manufacturer address and contact details	3-100 Akatsuki-cho, Seto Aichi 489-0071 Japan
Single Registration Number (SRN)	JP-MF-000010199

Authorised Representative name	Emergo Europe B.V.
Authorised Representative address and contact details	Westervoortsedijk 60 6827 AT Arnhem The Netherlands
Single Registration Number (SRN)	NL-AR-000000116

Notified body name	DEKRA Certification B.V.
Notified body number	0344
Directive Certificate number(s) to which this confirmation is made	2107788CE23/2107788DE19
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	05 July 2023
End date of extended validity/transition period	31 December 2027

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached list and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached list

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☑ Expired/expires *after* 20 March 2023:

☑ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached list or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

  ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

  ☑ A QMS in accordance with Article 10(9) MDR is in place.

  ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached list**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

ASAHI INTECC CO., LTD.

Aichi, Japan, 17 August 2023

Place and date of issue

Yasuyuki Kawahara
Person responsible for regulatory compliance

List of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device	
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6S80
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6S
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6SL
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6S110
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6A80
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6A
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6AL
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6A110
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7S80
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7S
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7SL
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7S110
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7A80
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7A
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7AL
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7A110
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 8Fr	WAIN-FBK-8S80
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 8Fr	WAIN-FBK-8S
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 8Fr	WAIN-FBK-8SL
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 8Fr	WAIN-FBK-8S110

Revision History

Ver.	Date	Description
1	8 June 2023	Newly established
2	17 August 2023	Removal of the catalog numbers for stiff type. Change of end date of extended validity/transition period due to the completion of MDR application agreement with the notified body.

Jan. 30, 2024

DECLARATION OF CONFORMITY (MDD)

1. Name and address of the firm: ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

We declare under our sole responsibility that

the medical device: (Name) ASAHI Neurovascular Guide Wire
(Model) WAIN-CKI-200 ASAHI CHIKAI 200cm
WAIN-CKI-300 ASAHI CHIKAI 300cm
WAIN-CKI-10-200 ASAHI CHIKAI 10 200cm
WAIN-CKI-10-300 ASAHI CHIKAI 10 300cm
(Serial of Lot No.)
From 29103-12721 to
Name, type or model, batch or serial number, possibly source and number of items

of Class: III
According to Rule 7 in annex IX of directive 93/42/EEC

meets all the provisions of the directive 93/42/EEC which apply it.

2. EC Design Examination Certificate No.: 2107788DE14
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

3. CE Marking of Conformity Certificate No.: 2107788CE16
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

4. Manufacturing Facility: (1) ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN
(2) ASAHI INTECC (THAILAND) CO., LTD.
158/1 Moo 5, Bangkadi Industrial Park Tiwanon Road, Tambol Bangkadi
Amphur Muang Pathumthani 12000 Thailand
(3) ASAHI INTECC HANOI CO., LTD.
THANG LONG Industrial Park Dong Anh District Hanoi Vietnam

5. Authorized representative in EU: Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands

6. Applied harmonized standards, national standards or other normative documents: Refer to Table 1 and Table 2

7. Conformity assessment procedure: Based on Medical Devices Directive 93/42/EEC Annex II 3 and 4

8. Signature of Manufacturer

3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN
January 18, 2021
Place, Date

Yasuyuki Kawahara,
General Manager
Quality Assurance Division
ASAHI INTECC CO., LTD.

Table 1: Applied harmonized standards (QA-Related Standards)

Standard Reference	Title
EN ISO 13485:2016 A: 2016 ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EC Directive 93/42/EEC:1993 /Amd1:1998 /Amd2:2000 /Amd3:2002 /Amd4:2003 /Amd5:2007	Medical Devices Directive (2007)

Table 2: Applied harmonized standards (Product related standards）

Standard Reference	Title
EN 556-1:2001 AC: 2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 15223-1: 2016 C1:2017/C2:2017 ISO 15223-1: 2016 C1:2016/C2:2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008 A:2013	Information Supplied by the Manufacturer of Medical Devices
EN 62366-1:2015 C:2016	Medical devices – Part1: Application of usability engineering to medical devices

Standard Reference	Title
EN ISO 10993-1: 2009 AC:2010 **ISO 10993-1: 2009 AC:2010**	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-2: 2006 **ISO 10993-2: 2006**	Biological evaluation of medical devices – Part 2: Animal welfare requirements
EN ISO 10993-4: 2017 **ISO 10993-4:2017**	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5: 2009 **ISO 10993-5: 2009**	Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity
EN ISO 10993-7: 2008 AC:2009 **ISO 10993-7: 2008 C1:2009/A1:2019**	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10: 2013 **ISO 10993-10: 2010**	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11: 2018 **ISO 10993-11: 2017**	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12: 2012 **ISO 10993-12: 2012**	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 11070: 2014 A1:2018 **ISO 11070: 2014 A1:2018**	Sterile single-use intravascular introducers, dilators and guidewires
EN ISO 11135: 2014 A1:2019 **ISO 11135: 2014 AMENDMENT1:2018**	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-1: 2017 **ISO 11138-1: 2017**	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2: 2017 **ISO 11138-2: 2017**	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11138-7: 2019 **ISO 11138-7: 2019**	Sterilization of Health Care Products - Biological Indicators – Part 7: Guidance for the Selection, Use and Interpretation of Results
EN ISO 11607-1: 2017 **ISO 11607-1: 2006 A:2014**	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2: 2017 **ISO 11607-2: 2006 A:2014**	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1: 2018 C:2018 **ISO 11737-1: 2018**	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products

Standard Reference	Title
EN ISO 11737-2: 2009 **ISO 11737-2: 2009**	Sterilization of medical devices – Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14155: 2011 **AC: 2011** **ISO 14155: 2011** **C: 2011**	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 14644-1: 2015 **ISO 14644-1: 2015**	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness by Particle Concentration
EN ISO 14644-2: 2015 **ISO 14644-2: 2015**	Cleanrooms and Associated Controlled Environments - Part 2: Monitoring to Provide Evidence of Cleanroom Performance Related to Air Cleanliness by Particle Concentration
EN ISO 14644-3: 2019 **ISO 14644-3: 2019**	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14698-1: 2003 **C:2003** **ISO 14698-1: 2003**	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
EN ISO 14698-2: 2003 **/AC: 2006** **ISO 14698-2: 2003** **/C: 2004**	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
EN ISO 14971: 2019 **ISO 14971: 2019**	Medical devices – Application of risk management to medical devices
MEDDEV. 2.12-1: 2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
MEDDEV.2.7/1: 2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
MEDDEV.2.12-2:2012	POST MARKET CLINICAL FOLLOW-UP STUDIES

Addendum to the original Declaration of Conformity (MDD)

The following changes have been made on the respective dates:

<table>
<tr><th>Date of Change</th><th>Descriptions</th><th>Corresponding Version</th></tr>
<tr><td>June 25, 2021</td><td>-The applicable standards were updated to the following:
EN ISO 11607-1: 2020
ISO 11607-1: 2019
ISO 11607-2: 2019</td><td>AMM-Q285 Ver.11</td></tr>
<tr><td>October 22, 2021</td><td>-The title of the company representative was changed from “General Manager” to “Person responsible for regulatory compliance.”

-The address of ASAHI INTECC (THAILAND) CO., LTD. was corrected.
<table><tr><td>Before</td><td>158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi
Amphur Muang, Pathumthani 12000 Thailand</td></tr><tr><td>After</td><td>158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi
Amphur Muang Pathumthani, Pathumthani 12000 Thailand</td></tr></table>-ISO 10993-18:2020 and EN ISO 10993-18:2020 were added to Table 2.

-The applicable standards were updated to the following:
EN ISO 10993-1:2020
ISO 10993-1: 2018
EN ISO 11737-2: 2020
ISO 11737-2: 2019
EN 62366-1:2015 /A1:2020</td><td>AMM-Q285 Ver.12</td></tr>
<tr><td>March 8, 2022</td><td>-The applicable standards were updated to the following:
EN ISO 10993-12: 2021
ISO 10993-12: 2021
EN ISO 11737-1: 2018 A:2021
ISO 11737-1: 2018 A:2021</td><td>AMM-Q285 Ver.13</td></tr>
<tr><td>June 9, 2022</td><td>-The applicable standards were updated to the following:
EN ISO 10993-7: 2008 A1:2022
EN ISO 14971: 2019 A11:2021</td><td>AMM-Q285 Ver.14</td></tr>
<tr><td>September 14, 2022</td><td>-The applicable standards were updated to the following:
ISO 10993-10: 2021
ISO10993-18:2020 A1:2021</td><td>AMM-Q285 Ver.15</td></tr>
</table>

Addendum to the original Declaration of Conformity (MDD)

<table>
<tr><th>Date of Change</th><th>Descriptions</th><th>Corresponding Version</th></tr>
<tr><td>June 1, 2023</td><td>-The applicable standards were updated to the following due to the wrong description:
EN ISO 10993-1: 2009 AC: 2010
ISO 10993-1: 2009 Cor1: 2010
EN ISO 10993-7: 2008 AC:2009
EN ISO 10993-18: 2009
ISO 10993-18: 2005
EN ISO 11607-1: 2017
ISO 11607-1: 2006 Amd1: 2014
ISO 11607-2: 2006 Amd1: 2014

-As of January 31, 2023, the address of our EU Authorized Representative as listed on the original DoC has been changed.
<table><tr><td>Name of company</td><td>Emergo Europe B.V.</td></tr><tr><td>Old Address</td><td>Prinsessegracht 20, 2514 AP The Hague, The Netherlands</td></tr><tr><td>New Address</td><td>Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands</td></tr></table></td><td>AMM-Q285 Ver.16</td></tr>
<tr><td>January 30, 2024</td><td>-The applicable standards were updated to the following:
EN ISO 10993-2: 2022
ISO 10993-2: 2022
EN ISO 10993-10: 2023

-ISO 10993-23:2021 and EN ISO 10993-23:2021 were added to Table 2.</td><td>NA</td></tr>
</table>

Aichi, Japan, January 30, 2024

Place and date of issue

Yasuyuki Kawahara
Person responsible for regulatory compliance
ASAHI INTECC CO., LTD.

EC CERTIFICATE

Number: 2107788CE16

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)

Guidewires for Neuro Vascular 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 28 September 2011

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 October 2022
Issued for the first time: 28 September 2011
Reissued: 1 October 2017

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
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: 2107788CE16

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Guidewires for Neuro Vascular 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 Neurovascular Guide Wire

Catalog No.	Brand Name
WAIN-CKI-200	ASAHI CHIKAI 200cm
WAIN-CKI-300	ASAHI CHIKAI 300cm
WAIN-CKI-10-200	ASAHI CHIKAI 10 200cm
WAIN-CKI-10-300	ASAHI CHIKAI 10 300cm
WAIN-CKI-008-200	ASAHI CHIKAI 008
WAIN-CKI-18-200-BS	ASAHI CHIKAI black 18
WAIN-CKI-200-BS	ASAHI CHIKAI black
WAIN-CKI-200-BA	ASAHI CHIKAI black
WAIN-CKI-200-RC	ASAHI CHIKAI
WAIN-CKI-300-RC	ASAHI CHIKAI
AIN-CKI-200-B-SFT	ASAHI CHIKAI black 14 soft tip
AIN-CKI-18-200-SFT	ASAHI CHIKAI black 18 soft tip
AIN-CKX-10-200-R	ASAHI CHIKAI X010

Initial date: 28 September 2011
Revision date: 31 May 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
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

ASAHI INTECC CO., LTD.

3-100 Akatsuki-cho,

Seto, Aichi 489-0071

Japan

06-Jul-23

Notified Body Confirmation Letter

Reference: EU2023-607/647139

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

ASAHI INTECC CO., LTD.
3-100 Akatsuki-cho,
Seto, Aichi 489-0071
Japan

SRN Number: JP-MF-000010199

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been

withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Firmato digitalmente da
Benedetta Romanelli
Data: 2023.07.06
11:55:32 +02'00'

Benedetta Romanelli

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
FUBUKI Neurovascular Guide Catheter	Class III	N/A	FQA: 2107788CE23 05-Jul-2023 DE: 2107788DE19 05-Jul-2023 NB DEKRA – 0344
Neurovascular Guide Wire	Class III	N/A	FQA: 2107788CE16 01-Oct-2022 DE: 2107788DE14 01-Oct-2022 NB DEKRA – 0344

Confirmation Letter Revision History

Date	Action
2023/07/06	Initial issue