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.

Digitally signed by Grabazei Alexandru
Date: 2024.04.03 17:00:32 EEST
Reason: MoldSign Signature
Location: Moldova

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