Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 3 din 11.07.2023

Solicitantul FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6, tel./fax: 022-273712, e-mail: contact@datacontrol.md
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1) Asahi Fubuki

WAIN-FBK-6A
WAIN-FBK-6AH
WAIN-FBK-6S
WAIN-FBK-6A80
WAIN-FBK-6A80H
WAIN-FBK-6S80
WAIN-FBK-6AL
WAIN-FBK-6ALH
WAIN-FBK-6SL
WAIN-FBK-6A110
WAIN-FBK-6A110H
WAIN-FBK-6S110
WAIN-FBK-7A
WAIN-FBK-7AH
WAIN-FBK-7S
WAIN-FBK-7A80
WAIN-FBK-7A80H
WAIN-FBK-7S80
WAIN-FBK-7AL
WAIN-FBK-7ALH
WAIN-FBK-7SL
WAIN-FBK-7A110
WAIN-FBK-7A110H
WAIN-FBK-7S110
WAIN-FBK-8S
WAIN-FBK-8S80
WAIN-FBK-8SL
WAIN-FBK-8S110
WAIN-FBK-4-120
WAIN-FBK-4-125
WAIN-FBK-4-130
WAIN-FBK-4AD
WAIN-FBK-4ADH
WAIN-FBK-4SD
WAIN-FBK-4AD80
WAIN-FBK-4AD80H

Digitally signed by Grabazei Alexandru
Date: 2023.07.12 09:34:44 EEST
Reason: MoldSign Signature
Location: Moldova

WAIN-FBK-4SD80
WAIN-FBK-4ADL
WAIN-FBK-4ADLH
WAIN-FBK-4SDL
WAIN-FBK-4AD110
WAIN-FBK-4AD110H
WAIN-FBK-4SD110
WAIN-FBK-5AD
WAIN-FBK-5ADH
WAIN-FBK-5SD
WAIN-FBK-5AD80
WAIN-FBK-5AD80H
WAIN-FBK-5SD80
WAIN-FBK-5ADL
WAIN-FBK-5ADLH
WAIN-FBK-5SDL
WAIN-FBK-5AD110
WAIN-FBK-5AD110H
WAIN-FBK-5SD110
WAIN-FBK-6SD
WAIN-FBK-6SD80
WAIN-FBK-6SDL
WAIN-FBK-6SD110

Se anexează următoarele acte:

1) Declarație de Conformitate, din 05.11.2015;
2) Certificarte CE no. 2107788CE24 din 01.05.2019.
3) Actul prin care producătorul își desemnează reprezentantul din 08.07.2021

Data 11.07.2023 Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1) Asahi Fubuki

WAIN-FBK-6A
WAIN-FBK-6AH
WAIN-FBK-6S
WAIN-FBK-6A80
WAIN-FBK-6A80H
WAIN-FBK-6S80
WAIN-FBK-6AL
WAIN-FBK-6ALH
WAIN-FBK-6SL
WAIN-FBK-6A110
WAIN-FBK-6A110H
WAIN-FBK-6S110
WAIN-FBK-7A
WAIN-FBK-7AH
WAIN-FBK-7S
WAIN-FBK-7A80
WAIN-FBK-7A80H
WAIN-FBK-7S80
WAIN-FBK-7AL
WAIN-FBK-7ALH
WAIN-FBK-7SL
WAIN-FBK-7A110
WAIN-FBK-7A110H
WAIN-FBK-7S110
WAIN-FBK-8S
WAIN-FBK-8S80
WAIN-FBK-8SL
WAIN-FBK-8S110
WAIN-FBK-4-120
WAIN-FBK-4-125
WAIN-FBK-4-130

WAIN-FBK-4AD
WAIN-FBK-4ADH
WAIN-FBK-4SD
WAIN-FBK-4AD80
WAIN-FBK-4AD80H
WAIN-FBK-4SD80
WAIN-FBK-4ADL
WAIN-FBK-4ADLH
WAIN-FBK-4SDL
WAIN-FBK-4AD110
WAIN-FBK-4AD110H
WAIN-FBK-4SD110
WAIN-FBK-5AD
WAIN-FBK-5ADH
WAIN-FBK-5SD
WAIN-FBK-5AD80
WAIN-FBK-5AD80H
WAIN-FBK-5SD80
WAIN-FBK-5ADL
WAIN-FBK-5ADLH
WAIN-FBK-5SDL
WAIN-FBK-5AD110
WAIN-FBK-5AD110H
WAIN-FBK-5SD110
WAIN-FBK-6SD
WAIN-FBK-6SD80
WAIN-FBK-6SDL
WAIN-FBK-6SD110

Se anexează următoarele acte:

1) Declarație de Conformitate, din 05.11.2015;
2) Certificarte CE no. 2107788CE24 din 01.05.2019.
3) Actul prin care producătorul își desemnează reprezentantul din 08.07.2021

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Grabazei Alexandru, director general. *Data 11.07.2023*

Str. Grigore Mora nr.34, sector 1, Bucuresti
Tel/Fax: 021 12 37 38 Tel/Fax: 021 211 48 49
Email: office@tecmed.ro

SCRISOARE DE AUTORIZARE

08.07.2021

Subscrisa **SC.TECMED SRL**, RO1578232, J40/2946/1992, cu sediul social in Str. Dr. Grigore Mora 34, sector 1, Bucuresti, Romania 01188 si punct de lucru Str. Gheorghe Bratianu nr.30, parter, sector 1, Bucuresti, Romania 011413, **"FURNIZOR DISPOZITVE MEDICALE"**,

Prin prezenta numesc **"SUB-DISTRIBUITOR"**: FCPC "DataControl" SRL cu sediul in Str. Melestiu nr.20, MD-2001, Chisinau, Republic Moldova autorizat sa inregistreze, sa re-inregistreze sau sa aduca modificari dispozitivelor inregistrate, sa comercializeze si sa promoze urmatoarele dispozitive cu marcaj CE, conform Contractului de Sub-distributie E55 nr. din 15.06.2019 si Anexele in vigoare:

- Portofoliu neurovascular **MicroVention – produse noi:**

Microghiduri neurovasculare: TRAXCESS 7 MINI

Microcatetere neurovasculare: WEDGE

Catetere de acces distal cu aspiratie: SOFIA EX

Micro Balon cu dublu-lumen: SCEPTER MINI

Stent intraluminal: LVIS EVO

Stent revascularizare: FRED X

Prin prezenta FCPC "DataControl" SRL este autorizata sa inregistreze dispozitivele sus-numite la autoritatile competente conform legislatiei in vigoare in Republica Moldova. Certificatele de inregistrare vor fi emise in numele SC. TECMED SRL, conform documentelor de calitate emise de producatorul MICROVENTION.

Scrisoare de Autorizare este valabila pentru o perioada de 24 de luni de la data semnarii acestui document, daca nu este revocat intre timp de catre una dintre parti.

TECMED SRL

Gheorghe Diaconu,
Administrator

Societatea Comerciala TECMED S.R.L. Romania

TECMED S.R.L.
INTRARE/IEŞIRE NR. 105
Ziua 08 Luna 07 Anul 2021

EC CERTIFICATE

Number: 2107788CE24

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)

Microcatheters for peripheral and coronary vasculatures

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2107788CN
Addendum, initially dated 26 April 2016

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 May 2024
Issued for the first time: 26 April 2016
Reissued: 1 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

ADDENDUM

Belonging to certificate: 2107788CE24

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Microcatheters for peripheral and coronary vasculatures

Issued to:

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

This certificate covers the following product(s):

ASAHI Caravel Microcatheter

Catalogue No.	Product Description
CRV135-19P	2.6Fr, Straight-Tip, 135 cm
CRV150-19P	2.6Fr, Straight-Tip, 150 cm

Initial date: 26 April 2016

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

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
Molenstraat 15, 2513 BH, 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
November 5, 2015
Place, Date

Yoshihiko Fukui,
Executive Director
Senior 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-6S11			110cm
	WAIN-FBK-6A80	ANGLED		80cm
	WAIN-FBK-6A			90cm
	WAIN-FBK-6AL			100cm
	WAIN-FBK-6A11			110cm
	WAIN-FBK-6A80	ANGLED	STIFF	80cm
	WAIN-FBK-6AH			90cm
	WAIN-FBK-6ALH			100cm
	WAIN-FBK-6A11			110cm
ASAHI FUBUKI 7Fr	WAIN-FBK-7S80	STRAIGHT	—	80cm
	WAIN-FBK-7S			90cm
	WAIN-FBK-7SL			100cm
	WAIN-FBK-7S11			110cm
	WAIN-FBK-7A80	ANGLED		80cm
	WAIN-FBK-7A			90cm
	WAIN-FBK-7AL			100cm
	WAIN-FBK-7A11			110cm
	WAIN-FBK-7A80	ANGLED	STIFF	80cm
	WAIN-FBK-7AH			90cm
	WAIN-FBK-7ALH			100cm
	WAIN-FBK-7A11			110cm
ASAHI FUBUKI 8Fr	WAIN-FBK-8S80	STRAIGHT	-	80cm
	WAIN-FBK-8S			90cm
	WAIN-FBK-8SL			100cm
	WAIN-FBK-8S11			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 13485:2012 AC: 2012 ISO 13485:2003 Cor1: 2009	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 5: 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 Amendment/Corrigendum
EN ISO 15223-1: 2012 ISO 15223-1: 2012	Medical devices- Symbols to be used with medical device labels, labeling and information to be supplied –Part 1: General requirements
EN 980:2008	Graphical Symbols for Use in the Labeling of Medical Devices
EN 1041:2008 Amd1:2013	Information Supplied by the Manufacturer with 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 - Lock fittings
EN 62366:2008	Medical devices – Application of usability engineering to medical devices
EN ISO 10555-1:2013 ISO 10555-1:2013	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 Cor1: 2010	Biological evaluation of medical devices – Part 1: Evaluation and testing

Standard Reference	Title
EN ISO 10993-2: 2006 **ISO 10993-2: 2006**	Biological evaluation of medical devices - Part 2: Animal welfare requirements
EN ISO 10993-4: 2009 **ISO 10993-4: 2002** **Amd 1: 2006**	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood AMENDMENT 1
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** **Cor1: 2009**	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 sensitization
EN ISO 10993-11: 2009 **ISO 10993-11: 2006**	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 **ISO 11135: 2014**	Sterilization of health care products -Ethylene oxide -Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-1: 2006 **ISO 11138-1: 2006**	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2: 2009 **ISO 11138-2: 2006**	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1: 2009 **Amd1:2014** **ISO 11607-1: 2006** **Amd1:2014**	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2: 2006 **Amd1:2014** **ISO 11607-2: 2006** **Amd1:2014**	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 14698-1: 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** **Cor1:2004**	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data

Standard Reference	Title
EN ISO 11737-1: 2006 AC: 2009 ISO 11737-1: 2006 Cor1: 2007	Sterilization of medical devices – Microbiological methods – Part 1: Estimation of population of microorganisms on products Corrigendum 1
EN ISO 11737-2: 2009 ISO 11737-2: 2009	Sterilization of medical devices – Microbiological methods -- Part 2: Tests of sterility performed in the validation 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 14161: 2009 ISO 14161: 2009	Sterilization of Health Care Products - Biological Indicators - Guidance for the Selection, Use and Interpretation of Results
EN ISO 14644-1: 1999 ISO 14644-1: 1999	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness
EN ISO 14644-2: 2000 ISO 14644-2: 2000	Cleanrooms and Associated Controlled Environments - Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1
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 device – Application of risk management to medical devices
MEDDEV. 2.12-1: 2013	GUIDELINES ON A MEDICAL DEVICE VIGILANCE SYSTEM
MEDDEV.2.12-2: 2012	POST MARKET CLINICAL FOLLOW-UP STUDIES
MEDDEV. 2.7.1: 2009	EVALUATION OF CLINICAL DATA: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

制定・改訂履歴

Ver.	制定・改訂日	内容
1	November 5, 2015	・ 新規制定