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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 6 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**
CHIKAI

WAIN-CKI-200
WAIN-CKI-200-RC
WAIN-CKI-200-BS
WAIN-CKI-200-BA

Se anexează următoarele acte:
1) Declarație de Conformitate, din 12.07.2013;
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 deţin 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**
   CHIKAI

   WAIN-CKI-200
   WAIN-CKI-200-RC
   WAIN-CKI-200-BS
   WAIN-CKI-200-BA

Se anexează următoarele acte:
1) Declarație de Conformitate, din 12.07.2013;
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

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) NEO'S PTCA Guide Wire
(Series) ASAHI PTCA GUIDE WIRE AG, AGH, and AGP series
(Model) Refer to Table 1
(Serial of Lot No.)
From 8404810031 to
Name, type or model, batch or serial number, possibly source and number of items

of Class: III
According to 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.: 2107788DE01
Issued by: DEKRA Certification B. V. (Notified under No. 0344)

3. CE Marking of Conformity Certificate No.: 2107788CE01
Issued by: DEKRA Certification B. V. (Notified under No. 0344)

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

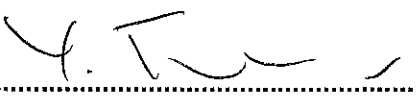
5. Authorized representative in EU: Emergo Europe
Molenstraat 15, 2513 BH, The Hague, The Netherlands

6. Applied harmonized standards, national standards or other normative documents: Refer to Table 2 and Table 3

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
July 12, 2013
Place, Date



Yoshihiko Fukui,
Executive Director
Senior General Manager
Quality Assurance Division
ASAHI INTECC CO., LTD.

Table 1 Model of ASAHI PTCA GUIDE WIRE

Product No.	Product Name	Product No.	Product Name
12780-01 (AG141000)	ASAHI SOFT 180cm	14939-01 (AG141300)	ASAHI SOFT 300cm
12780-02 (AG141000J)	ASAHI SOFT 180cm J	14939-02 (AG141300J)	ASAHI SOFT 300cm J
12781-01 (AG141002)	ASAHI GRAND SLAM 180cm	14940-01 (AG141302)	ASAHI GRAND SLAM 300cm
12781-02 (AG141002J)	ASAHI GRAND SLAM 180cm J	14940-02 (AG141302J)	ASAHI GRAND SLAM 300cm J
12782-01 (AG142000)	ASAHI MEDIUM 180cm	14941-01 (AG142300)	ASAHI MEDIUM 300cm
- (AG142000J)	ASAHI MEDIUM 180cm J	- (AG142300J)	ASAHI MEDIUM 300cm J
12783-01 (AG143000)	ASAHI STANDARD 180cm	14942-01 (AG143300)	ASAHI STANDARD 300cm
- (AG143000J)	ASAHI STANDARD 180cm J	- (AG143300J)	ASAHI STANDARD 300cm J
12785-01 (AG145000)	ASAHI LIGHT 180cm	14944-01 (AG145300)	ASAHI LIGHT 300cm
12785-02 (AG145000J)	ASAHI LIGHT 180cm J	14944-02 (AG145300J)	ASAHI LIGHT 300cm J
12778-01 (AG14M050)	ASAHI MIRACLEbros 3 180cm	14937-01 (AG14M350)	ASAHI MIRACLEbros 3 300cm
- (AG14M050J)	ASAHI MIRACLEbros 3 180cm J	- (AG14M350J)	ASAHI MIRACLEbros 3 300cm J
12777-01 (AG14M045)	ASAHI MIRACLEbros 4.5 180cm	14936-01 (AG14M345)	ASAHI MIRACLEbros 4.5 300cm
- (AG14M045J)	ASAHI MIRACLEbros 4.5 180cm J	- (AG14M345J)	ASAHI MIRACLEbros 4.5 300cm J
12779-01 (AG14M060)	ASAHI MIRACLEbros 6 180cm	14938-01 (AG14M360)	ASAHI MIRACLEbros 6 300cm
- (AG14M060J)	ASAHI MIRACLEbros 6 180cm J	- (AG14M360J)	ASAHI MIRACLEbros 6 300cm J
82903-01 (AG14M070)	ASAHI MIRACLEbros 12 180cm	82903-02 (AG14M370)	ASAHI MIRACLEbros 12 300cm
- (AG14M070J)	ASAHI MIRACLEbros 12 180cm J	- (AG14M370J)	ASAHI MIRACLEbros 12 300cm J
12784-01 (AG143090)	ASAHI CONFIANZA 180cm	14943-01 (AG143390)	ASAHI CONFIANZA 300cm
- (AG143090J)	ASAHI CONFIANZA 180cm J	- (AG143390J)	ASAHI CONFIANZA 300cm J
20629-01 (AGH143090)	ASAHI CONFIANZA PRO 180cm	20629-02 (AGH143390)	ASAHI CONFIANZA PRO 300cm
- (AGH143090J)	ASAHI CONFIANZA PRO 180cm J	— (AGH143390J)	ASAHI CONFIANZA PRO 300cm J
82902-01 (AGH143091)	ASAHI CONFIANZA PRO 12 180cm	82902-02 (AGH143391)	ASAHI CONFIANZA PRO 12 300cm
- (AGH143091J)	ASAHI CONFIANZA PRO 12 180cm J	- (AGH143391J)	ASAHI CONFIANZA PRO 12 300cm J
12776-01 (AGH146000)	ASAHI PROWATER 180cm	14935-01 (AGH146300)	ASAHI PROWATER 300cm
12776-02 (AGH146000J)	ASAHI PROWATER 180cm J	14935-02 (AGH146300J)	ASAHI PROWATER 300cm J
82358-01 (AGH147000)	ASAHI PROWATERflex 180cm	82358-02 (AGH147300)	ASAHI PROWATERflex 300cm
82358-11 (AGH147000J)	ASAHI PROWATERflex 180cm J	82358-12 (AGH147300J)	ASAHI PROWATERflex 300cm J
82359-01 (AGP140000)	ASAHI FIELDER 180cm	82359-02 (AGP140300)	ASAHI FIELDER 300cm
82359-11 (AGP140000J)	ASAHI FIELDER 180cm J	82359-12 (AGP140300J)	ASAHI FIELDER 300cm J

Product No.	Product Name	Product No.	Product Name
1011895H (AGP140001)	ASAHI FIELDER FC 180cm	1011896H (AGP140301)	ASAHI FIELDER FC 300cm
1011895HJ (AGP140001J)	ASAHI FIELDER FC 180cm J	1011896HJ (AGP140301J)	ASAHI FIELDER FC 300cm J
AGP140002	ASAHI FIELDER XT 190cm	AGP140302	ASAHI FIELDER XT 300cm

Table 2 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 L 169 1993 Amd 1: 1998 Amd 2: 2000 Amd 3: 2002 Amd 4: 2003 Amd 5: 2007	Medical Devices Directive (2007)

Table 3 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 556-2: 2003	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- Part 2: Requirements for aseptically processed medical devices
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 –Part1: General requirements
EN 1041:2008	Terminology, symbols and information provided with medical devices - Information Supplied by the Manufacturer
EN ISO 10993-1: 2009 AC: 2010 ISO 10993-1: 2009 Cor1: 2010	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-2: 2006 ISO 10993-2: 2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements – Second Edition
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 cytotoxicity: *in vitro* methods
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: 2010 ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization

Standard Reference	Title
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 11070: 1999 **ISO 11070: 1998**	Sterile, single-use intravascular catheter introducers
EN ISO 11135-1:2007 **ISO 11135-1:2007**	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 **ISO11138-1: 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 **ISO 11607-1: 2006**	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems-First edition
EN ISO 11607-2: 2006 **ISO 11607-2: 2006**	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes-First edition
EN ISO 11737-1: 2006 AC:2009 **ISO 11737-1: 2006 Cor 1: 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-First Edition
EN ISO 14644-1: 1999 **ISO 14644-1: 1999**	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness-First Edition
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-First Edition
EN ISO 14644-3: 2005 **ISO 14644-3: 2005**	Cleanrooms and associated controlled environments - Part 3: Test methods-First Edition
EN ISO 14698-1: 2003 **ISO 14698-1: 2003**	Cleanrooms and associated controlled environments Biocontamination control - Part 1: General principles and methods - First Edition
EN ISO 14698-2: 2003 AC: 2006 **ISO 14698-2: 2003 Cor1: 2004**	Cleanrooms and associated controlled environments Biocontamination control - Part 1: General principles and methods - First Edition
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. 2.7.1: 2009	EVALUATION OF CLINICAL DATA: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
MEDDEV. 2.12-2: 2012	POST MARKET CLINICAL FOLLOW-UP STUDIES

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

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T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396