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) Peripheral Guide Wires
(Model) ASAHI Peripheral Guide Wire (Refer to Table 1 in page 2/4)
(Serial of Lot No. / Product catalog No.)
From 160706A101 / PPW14R100P to
Name, type or model, batch or serial number, possibly source and number of items

of Class: IIa
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. CE Marking of Conformity Certificate No.: 2107788CE11
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

3. 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

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

5. Applied harmonized standards, national standards or other normative documents: Refer to Table 2 in page 3/4-4/4

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

7. Signature of Manufacturer

3-100, Akatsuki-cho, Seto, Aichi 489-0071, JAPAN
February 24 , 2021
Place, Date

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

Table 1. Model of ASAHI Peripheral Guide Wire

ASAHI Peripheral Guide Wire		
Product name	Catalog No.	Brand Name
ASAHI Gladius	PPW14R100S	ASAHI Peripheral Guide Wire ASAHI Gladius
	PPW14R200S	
	PPW14R300S	
	PPW18R100S	
	PPW18R200S	
	PPW18R300S	
	PPW14R100P	
	PPW14R200P	
	PPW14R300P	
	PPW18R100P	
	PPW18R200P	
	PPW18R300P	
ASAHI Halberd	PHW14R101S	ASAHI Peripheral Guide Wire ASAHI Halberd
	PHW14R201S	
	PHW14R301S	
	PHW18R101S	
	PHW18R201S	
	PHW18R301S	
	PHW14R101P	
	PHW14R201P	
	PHW14R301P	
	PHW18R101P	
	PHW18R201P	
	PHW18R301P	
ASAHI Gaia PV	PHW18R102S	ASAHI Peripheral Guide Wire ASAHI Gaia PV
	PHW18R202S	
	PHW18R302S	
	PHW18R102P	
	PHW18R202P	
	PHW18R302P	
Astato XS 40	PAGHW143094	ASAHI Peripheral Guide Wire Astato XS 40
	PAGHW143394	

Table 2. Applied harmonized standards

1. 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 Amd 1: 1998 Amd 2: 2000 Amd 3: 2002 Amd 4: 2003 Amd 5: 2007	Medical Devices Directive (2007)

2. 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

Standard Reference	Title
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
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:

<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-CD031 Ver.8</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-CD031 Ver.9</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 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</td><td>AMM-CD031 Ver.10</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-CD031 Ver.11</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 10993-7: 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-CD031 Ver.12</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.