

*Jan. 30, 2024*



## DECLARATION OF CONFORMITY (MDD)

1. Name and address of the firm .....  
 ASAHI INTECC CO., LTD.  
 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 2/5)  
 (Serial of Lot No. / Product catalog No.)  
 From 200410A011 / PP14R003P 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 (THAILAND) CO., LTD.  
 158/1 Moo 5, Bangkadi Industrial Park Tiwanon Road, Tambol Bangkadi  
 Amphur Muang, Pathumthani 12000 Thailand

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 3/5-5/5

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  
 January 18, 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 ASAHI ペリフェラルガイドワイヤー		
Product name 製品名	Catalog No. カタログ番号	Brand Name ブランドネーム
ASAHI Gladius MG 14 PV	PP14R003P PP14R203P PP14R303P PP14R003S PP14R203S PP14R303S	ASAHI Peripheral Guide Wire ASAHI Gladius MG 14 PV
ASAHI Gladius MG 14 PV ES	PP14R004P PP14R204P PP14R304P PP14R004S PP14R204S PP14R304S	ASAHI Peripheral Guide Wire ASAHI Gladius MG 14 PV ES
ASAHI Gladius MG 18 PV ES	PP18R004P PP18R204P PP18R304P PP18R004S PP18R204S PP18R304S	ASAHI Peripheral Guide Wire ASAHI Gladius MG 18 PV ES

**Table 2. Applied harmonized standards****1. QA-RELATED STANDARDS**

Standard Reference	Title
<b>EN ISO 13485: 2016</b> <b>A:2016</b> <b>ISO 13485: 2016</b>	Medical devices -- Quality management systems -- Requirements for regulatory purposes
<b>EC Directive</b> <b>93/42/EEC :1993</b> <b>Amd 1: 1998</b> <b>Amd 2: 2000</b> <b>Amd 3: 2002</b> <b>Amd 4: 2003</b> <b>Amd 5: 2007</b>	Medical Devices Directive (2007)

**2. PRODUCT-RELATED STANDARDS**

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

Standard Reference	Title
<b>EN ISO 10993-17: 2009</b> <b>ISO 10993-17: 2002</b>	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
<b>EN ISO 10993-18: 2020</b> <b>ISO 10993-18:2020</b>	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
<b>EN ISO 11070: 2014</b> <b>A1: 2018</b> <b>ISO 11070: 2014</b> <b>A1: 2018</b>	Sterile single-use intravascular introducers, dilators and guidewires
<b>EN ISO 11135: 2014</b> <b>A1:2019</b> <b>ISO 11135: 2014</b> <b>AMENDMENT1:2018</b>	Sterilization of health care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
<b>EN ISO 11138-1: 2017</b> <b>ISO 11138-1: 2017</b>	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
<b>EN ISO 11138-2: 2017</b> <b>ISO 11138-2: 2017</b>	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
<b>EN ISO 11138-7: 2019</b> <b>ISO 11138-7: 2019</b>	Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results
<b>EN ISO 11607-1: 2017</b> <b>ISO 11607-1: 2006</b> <b>A:2014</b>	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
<b>EN ISO 11607-2: 2017</b> <b>ISO 11607-2: 2006</b> <b>A:2014</b>	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
<b>EN ISO 11737-1: 2018</b> <b>C:2018</b> <b>ISO 11737-1: 2018</b>	Sterilization of health care products – Microbiological methods Part 1: Determination of a population of microorganisms on products
<b>EN ISO 11737-2: 2009</b> <b>ISO 11737-2: 2009</b>	Sterilization of medical devices – Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
<b>EN ISO 14155: 2011</b> <b>AC:2011</b> <b>ISO 14155:2011</b> <b>C:2011</b>	Clinical investigation of medical devices for human subjects- Good clinical practice
<b>EN ISO 14644-1: 2015</b> <b>ISO 14644-1: 2015</b>	Cleanrooms and Associated Controlled Environments - Part 1: Classification of air cleanliness by particle concentration
<b>EN ISO 14644-2: 2015</b> <b>ISO 14644-2: 2015</b>	Cleanrooms and Associated Controlled Environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
<b>EN ISO 14644-3: 2019</b> <b>ISO 14644-3: 2019</b>	Cleanrooms and associated controlled environments - Part 3: Test methods
<b>EN ISO 14698-1: 2003</b> <b>C:2003</b> <b>ISO 14698-1: 2003</b>	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
<b>EN ISO 14698-2: 2003</b> <b>AC: 2006</b> <b>ISO 14698-2: 2003</b> <b>C: 2004</b>	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data
<b>EN ISO 14971: 2019</b> <b>ISO 14971: 2019</b>	Medical devices – Application of risk management to medical devices
<b>MEDDEV. 2.12-1: 2013</b>	GUIDELINES ON A MEDICAL DEVICE VIGILANCE SYSTEM
<b>MEDDEV. 2.7/1: 2016</b>	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
<b>MEDDEV. 2.12-2: 2012</b>	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-CD053 Ver.4				
October 22, 2021	-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 border="1"><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> -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	Before	158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi Amphur Muang, Pathumthani 12000 Thailand	After	158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi Amphur Muang Pathumthani, Pathumthani 12000 Thailand	AMM-CD053 Ver.5
Before	158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi Amphur Muang, Pathumthani 12000 Thailand					
After	158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi Amphur Muang Pathumthani, Pathumthani 12000 Thailand					
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-CD053 Ver.6				
September 14, 2022	-The applicable standards were updated to the following: ISO 10993-10: 2021 ISO10993-18:2020 A1:2021	AMM-CD053 Ver.7				
June 1, 2023	- 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	AMM-CD053 Ver.13				

## Addendum to the original Declaration of Conformity (MDD)

Date of Change	Descriptions	Corresponding Version						
	<div>-As of January 31, 2023, the address of our EU Authorized Representative as listed on the original DoC has been changed.</div> <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>	Name of company	Emergo Europe B.V.	Old Address	Prinsessegracht 20, 2514 AP The Hague, The Netherlands	New Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands	
Name of company	Emergo Europe B.V.							
Old Address	Prinsessegracht 20, 2514 AP The Hague, The Netherlands							
New Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands							
January 30, 2024	<div>-The applicable standards were updated to the following: EN ISO 10993-2: 2022 ISO 10993-2: 2022 EN ISO 10993-10: 2023</div> <div>-ISO 10993-23:2021 and EN ISO 10993-23:2021 were added to Table 2.</div>	NA						

Aichi, Japan, January 30, 2024

Place and date of issue



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