




## 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 PTCA Guide Wire ASAHI Gaia  
 ..... (Model) Refer to Table 1  
 ..... (Serial of Lot No.)  
 ..... From A131021A011 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. .... 2107788DE17  
 Issued by .....  
 ..... DEKRA Certification B. V. (Notified under No. 0344)  
 ..... Arnhem, The Netherlands  
 .....

3. CE Marking of Conformity Certificate No. .... 2107788CE20  
 Issued by .....  
 ..... DEKRA Certification B. V. (Notified under No. 0344)  
 ..... Arnhem, The Netherlands  
 .....

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  
 .....

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 2 and 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  
 January 18, 2021  
 Place, Date

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

**Table 1 Model of ASAHI Gaia series**

Catalog No.	Product Name
AHW14R007S	ASAHI Gaia First
AHW14R007P	ASAHI Gaia First Pre-shape
AHW14R307S	ASAHI Gaia First 300cm
AHW14R307P	ASAHI Gaia First 300cm Pre-shape
AHW14R008S	ASAHI Gaia Second
AHW14R008P	ASAHI Gaia Second Pre-shape
AHW14R308S	ASAHI Gaia Second 300cm
AHW14R308P	ASAHI Gaia Second 300cm Pre-shape
AHW14R011S	ASAHI Gaia Third
AHW14R011P	ASAHI Gaia Third Pre-shape
AHW14R311S	ASAHI Gaia Third 300cm
AHW14R311P	ASAHI Gaia Third 300cm Pre-shape

**Table 2 Applied harmonized standards (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>Amd1:1998</b> <b>Amd2:2000</b> <b>Amd3:2002</b> <b>Amd4:2003</b> <b>Amd5:2007</b>	Medical Devices Directive (2007)

**Table 3 Applied harmonized standards (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 – Part 1: 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 – Part 1: 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 <i>in vitro</i> 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

Standard Reference	Title
<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
<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 DEVICES VIGILANCE SYSTEM

Standard Reference	Title
<b>MEDDEV. 2.12-2:2012</b>	POST MARKET CLINICAL FOLLOW-UP STUDIES
<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

## 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-Q300 Ver.10				
October 22, 2021	<div><div>-The title of the company representative was changed from “General Manager” to “Person responsible for regulatory compliance.”</div><div>-The address of ASAHI INTECC (THAILAND) CO., LTD. was corrected.</div><div><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></div><div>-ISO 10993-18:2020 and EN ISO 10993-18:2020 were added to Table 3.</div><div>-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</div></div>	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-Q300 Ver.11
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-Q300 Ver.12				
September 14, 2022	-The applicable standards were updated to the following: ISO 10993-10: 2021 ISO10993-18:2020 A1:2021	AMM-Q300 Ver.13				

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

Date of Change	Descriptions	Corresponding Version						
June 1, 2023	<p>-The applicable standards were updated to the following due to the wrong description:</p> <p>EN ISO 10993-7: 2008 AC:2009</p> <p>EN ISO 10993-18: 2009</p> <p>ISO 10993-18: 2005</p> <p>EN ISO 11607-1: 2017</p> <p>ISO 11607-1: 2006 Amd1: 2014</p> <p>ISO 11607-2: 2006 Amd1: 2014</p> <p>-As of January 31, 2023, the address of our EU Authorized Representative as listed on the original DoC has been changed.</p> <table><tr><td><b>Name of company</b></td><td>Emergo Europe B.V.</td></tr><tr><td><b>Old Address</b></td><td>Prinsessegracht 20, 2514 AP The Hague, The Netherlands</td></tr><tr><td><b>New Address</b></td><td>Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands</td></tr></table>	<b>Name of company</b>	Emergo Europe B.V.	<b>Old Address</b>	Prinsessegracht 20, 2514 AP The Hague, The Netherlands	<b>New Address</b>	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands	AMM-Q300 Ver.14
<b>Name of company</b>	Emergo Europe B.V.							
<b>Old Address</b>	Prinsessegracht 20, 2514 AP The Hague, The Netherlands							
<b>New Address</b>	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands							
January 30, 2024	<p>-The applicable standards were updated to the following:</p> <p>EN ISO 10993-2: 2022</p> <p>ISO 10993-2: 2022</p> <p>EN ISO 10993-10: 2023</p> <p>-ISO 10993-23:2021 and EN ISO 10993-23:2021 were added to Table 3.</p>	NA						

Aichi, Japan, January 30, 2024

Place and date of issue

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