

Jan. 30, 2024



DECLARATION OF CONFORMITY (MDD)

1. Name and address of the firm
 ASAHİ INTECC CO., LTD.
 3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

We declare under our sole responsibility that
 the medical device

(Name) PTCA Guide Wires
 (Model) ASAHİ Gladius (Refer to Table 1 in page 2/4)
 (Serial of Lot No. / Product catalog No.)
 From 200820A711/AP14R025P 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. 2107788DE24
 Issued by DEKRA Certification B. V. (Notified under No. 0344)
 Arnhem, The Netherlands

3. CE Marking of Conformity Certificate No. 2107788CE31
 Issued by DEKRA Certification B. V. (Notified under No. 0344)
 Arnhem, The Netherlands

4. Manufacturing Facility
 (1) ASAHİ 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 in page 2/4-4/4

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

[Signature]
 Yasuyuki Kawahara
 General Manager
 Quality Assurance Division
 ASAHİ INTECC CO., LTD.

Table 1. Model of ASAHI PTCA Guide Wire

Catalog No.	Product Name
AP14R023P	ASAHI Gladius MG14 190cm Pre-shape
AP14R323P	ASAHI Gladius MG14 300cm Pre-shape
AP14R023S	ASAHI Gladius MG14 190cm Straight
AP14R323S	ASAHI Gladius MG14 300cm Straight
AP14R024P	ASAHI Gladius MG14 ES 190cm Pre-shape
AP14R324P	ASAHI Gladius MG14 ES 300cm Pre-shape
AP14R024S	ASAHI Gladius MG14 ES 190cm Straight
AP14R324S	ASAHI Gladius MG14 ES 300cm Straight
AP14R025P	ASAHI Gladius EX14 200cm Pre-shape
AP14R325P	ASAHI Gladius EX14 300cm Pre-shape
AP14R025S	ASAHI Gladius EX14 200cm Straight
AP14R325S	ASAHI Gladius EX14 300cm Straight

Table 2. Applied standards

1. QA-RELATED STANDARDS

Standard Reference	Title
EN ISO 13485: 2016 AC: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 Cor1:2017/Cor2:2017 ISO 15223-1: 2016 Cor1:2016/Cor2:2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041: 2008 Amd1:2013	Information supplied by the manufacturer of medical devices
EN 62366-1:2015 Cor:2016	Medical devices – Part 1: Application of usability engineering to medical devices

Standard Reference	Title
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
EN ISO 10993-12: 2012 ISO 10993-12: 2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-17: 2009 ISO 10993-17: 2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18: 2020 ISO 10993-18: 2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
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 A1:2018	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 Amd1:2014	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 Amd1:2014	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes

Standard Reference	Title
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 Cor1:2011	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 Cor1:2003 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
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:

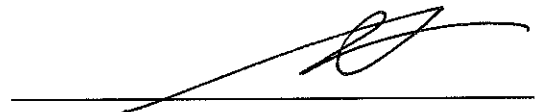
Date of Change	Descriptions	Corresponding Version				
June 25, 2021	-The applicable standards were updated to the following: EN ISO 11607-1: 2020 ISO 11607-1: 2019 ISO 11607-2: 2019	AMM-CD054 Ver.3				
October 22, 2021	-The title of the company representative was changed from “General Manager” to “Person 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-CD054 Ver.4
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-CD054 Ver.5				
September 14, 2022	-The applicable standards were updated to the following: ISO 10993-10: 2021 ISO10993-18:2020 A1:2021	AMM-CD054 Ver.6				
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-CD054 Ver.7				

Addendum to the original Declaration of Conformity (MDD)

Date of Change	Descriptions	Corresponding Version						
	<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>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	<p>-The applicable standards were updated to the following: EN ISO 10993-2: 2022 ISO 10993-2: 2022 EN ISO 10993-10: 2023</p> <p>-ISO 10993-23:2021 and EN ISO 10993-23:2021 were added to Table 2.</p>							

Aichi, Japan, January 30, 2024

Place and date of issue



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