



*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) ASAHI PTCA Guide Wire  
.....  
(Series) AG, AGH, and AGP series  
.....  
(Model) Refer to Table 1  
.....  
(Serial of Lot No.)  
.....  
From 93075-10011 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. .... 2107788DE01  
Issued by .....  
DEKRA Certification B. V. (Notified under No. 0344)  
Arnhem, The Netherlands

3. CE Marking of Conformity Certificate No. .... 2107788CE01  
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  
.....  
(3) ASAHI INTECC HANOI CO., LTD.  
THANG LONG Industrial Park Dong Anh District Hanoi Vietnam

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 PTCA Guide Wire**

Catalog No.	Brand Name	Catalog No.	Brand Name
AG141000	Soft	AG143090	Conquest
AG141000J	Soft J		Confianza CONFIANZA
AG141300	Soft 300cm	AG143090J	Conquest J
AG141300J	Soft 300cm J		Confianza J CONFIANZA J
AG141002	Grand Slam	AG143390	Conquest 300cm
AG141002J	Grand Slam J		Confianza 300cm CONFIANZA 300cm
AG141302	Grand Slam 300cm	AG143390J	Conquest 300cm J
AG141302J	Grand Slam 300cm J		Confianza 300cm J CONFIANZA 300cm J
AG142000	Intermediate	AGH143090	Conquest Pro
	Medium		Confianza Pro
	MEDIUM		CONFIANZA PRO
AG142000J	Intermediate J	AGH143090J	Conquest Pro J
	Medium J		Confianza Pro J
	MEDIUM J		CONFIANZA PRO J
AG142300	Intermediate 300cm	AGH143390	Conquest Pro 300cm
	Medium 300cm		Confianza Pro 300cm
	MEDIUM 300cm		CONFIANZA PRO 300cm
AG142300J	Intermediate 300cm J	AGH143390J	Conquest Pro 300cm J
	Medium 300cm J		Confianza Pro 300cm J
	MEDIUM 300cm J		CONFIANZA PRO 300cm J
AG143000	Standard	AGH143091	Conquest Pro 12
AG143000J	Standard J		Confianza Pro 12 CONFIANZA PRO 12
AG143300	Standard 300cm	AGH143091J	Conquest Pro 12 J
AG143300J	Standard 300cm J		Confianza Pro 12 J CONFIANZA PRO 12 J
AG145000	Light	AGH143391	Conquest Pro 12 300cm
AG145000J	Light J		Confianza Pro 12 300cm CONFIANZA PRO 12 300cm
AG145300	Light 300cm	AGH143391J	Conquest Pro 12 300cm J
AG145300J	Light 300cm J		Confianza Pro 12 300cm J CONFIANZA PRO 12 300cm J
AG14M050	Miracle 3	AGH146000	Rinato
	Miraclebros 3		Prowater
	MIRACLEbros 3		PROWATER
AG14M050J	Miracle 3 J	AGH146000J	Rinato J
	Miraclebros 3 J		Prowater J
	MIRACLEbros 3 J		PROWATER J
AG14M350	Miracle 3 300cm	AGH146300	Rinato 300cm
	Miraclebros 3 300cm		Prowater 300cm
	MIRACLEbros 3 300cm		PROWATER 300cm
AG14M350J	Miracle 3 300cm J	AGH146300J	Rinato 300cm J
	Miraclebros 3 300cm J		Prowater 300cm J
	MIRACLEbros 3 300cm J		PROWATER 300cm J
AG14M045	Miracle 4.5	AGH147000	Prowaterflex
	Miraclebros 4.5		Route
	MIRACLEbros 4.5		PROWATERflex
AG14M045J	Miracle 4.5 J	AGH147000J	Prowaterflex J
	Miraclebros 4.5 J		Route J
	MIRACLEbros 4.5 J		PROWATERflex J
AG14M345	Miracle 4.5 300cm	AGH147300	Prowaterflex 300cm
	Miraclebros 4.5 300cm		Route 300cm
	MIRACLEbros 4.5 300cm		PROWATERflex 300cm

AG14M345J	Miracle 4.5 300cm J	AGH147300J	Prowaterflex 300cm J
	Miraclebros 4.5 300cm J		Route 300cm J
	MIRACLEbros 4.5 300cm J		PROWATERflex 300cm J
AG14M060	Miracle 6	AHW14S003S	ULTIMATEbros 3
	Miraclebros 6	AHW14S003J	ULTIMATEbros 3 J
	MIRACLEbros 6		
AG14M060J	Miracle 6 J	AHW14S303S	ULTIMATEbros 3 300cm
	Miraclebros 6 J	AHW14S303J	ULTIMATEbros 3 300cm J
	MIRACLEbros 6 J		
AG14M360	Miracle 6 300cm	AGP140000	Fielder
	Miraclebros 6 300cm	AGP140000J	Fielder J
	MIRACLEbros 6 300cm		
AG14M360J	Miracle 6 300cm J	AGP140300	Fielder 300cm
	Miraclebros 6 300cm J	AGP140300J	Fielder 300cm J
	MIRACLEbros 6 300cm J		
AG14M070	Miracle 12	AGP140001	Fielder FC
	Miraclebros 12	AGP140001J	Fielder FC J
	MIRACLEbros 12		
AG14M070J	Miracle 12 J	AGP140301	Fielder FC 300cm
	Miraclebros 12 J	AGP140301J	Fielder FC 300cm J
	MIRACLEbros 12 J		
AG14M370	Miracle 12 300cm	AGP140002	Fielder XT
	Miraclebros 12 300cm	AGP140302	Fielder XT 300cm
	MIRACLEbros 12 300cm		
AG14M370J	Miracle 12 300cm J		
	Miraclebros 12 300cm J		
	MIRACLEbros 12 300cm J		

**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>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)

**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 – Part1: 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
<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

Standard Reference	Title
<b>EN ISO 11135: 2014 A1:2019 ISO 11135: 2014 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 ISO 11138-1: 2017</b>	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
<b>EN ISO 11138-2: 2017 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 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 ISO 11607-1: 2006 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 ISO 11607-2: 2006 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 C: 2018 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 ISO 11737-2: 2009</b>	Sterilization of health care products – Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
<b>EN ISO 14155: 2011 AC:2011 ISO 14155: 2011 C:2011</b>	Clinical investigation of medical devices for human subjects – Good clinical practice
<b>EN ISO 14644-1: 2015 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 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 ISO 14644-3: 2019</b>	Cleanrooms and associated controlled environments - Part 3: Test methods
<b>EN ISO 14698-1: 2003 C:2003 ISO 14698-1: 2003</b>	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
<b>EN ISO 14698-2: 2003 AC: 2006 ISO 14698-2: 2003 C: 2004</b>	Cleanrooms and associated controlled environments Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
<b>EN ISO 14971: 2019 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
<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:

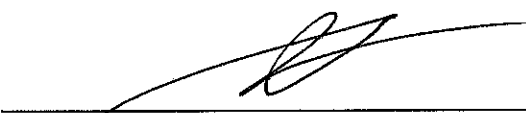
Date of Change	Descriptions	Corresponding Version				
June 25, 2021	-The applicable standards were updated to the following: EN ISO 11607-1: 2020 ISO 11607-1: 2019 ISO 11607-2: 2019	AMM-Q262 Ver.18				
October 22, 2021	<div><div>-The title of the company representative was changed from “General Manager” 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-Q262 Ver.19
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-Q262 Ver.20				
September 14, 2022	-The applicable standards were updated to the following: ISO 10993-10: 2021 ISO10993-18:2020 A1:2021	AMM-Q262 Ver.21				
November 25, 2022	-Serial of Lot No. "220708A191" was added.	AMM-Q262 Ver.22				

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

Date of Change	Descriptions		Corresponding Version
	Catalog No.	Brand Name	
	AGH143390J	Conquest Pro 300cm J	
		Confianza Pro 300cm J	
		CONFIANZA PRO 300cm J	
	AGH143091	Conquest Pro 12	
		Confianza Pro 12	
		CONFIANZA PRO 12	
	AGH143091J	Conquest Pro 12 J	
		Confianza Pro 12 J	
		CONFIANZA PRO 12 J	
	AGH143391	Conquest Pro 12 300cm	
		Confianza Pro 12 300cm	
		CONFIANZA PRO 12 300cm	
	AGH143391J	Conquest Pro 12 300cm J	
		Confianza Pro 12 300cm J	
		CONFIANZA PRO 12 300cm J	
December 15, 2023	-The last date of manufacture before the extension is stated.		AMM-Q262 Ver.25
January 30, 2024	-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 3.		NA

Aichi, Japan, January 30, 2024

Place and date of issue

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