

DECLARATION OF CONFORMITY (MDD)

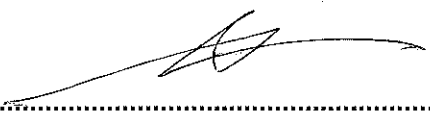
1.	Name and address of the firm	ASAHI INTECC CO., LTD. Medical Division 3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN
We declare under our sole responsibility that the medical device		(Name) ASAHI PTCA Guide Wire (Series) AG, AGH, and AGP series (Model) Refer to Table 1 (Serial of Lot No.) From 93075-10011 to 220708A191
of Class		III <small>According to Rule 7 in annex IX of directive 93/42/EEC</small>
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, 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	 Yasuyuki Kawahara, Person responsible for regulatory compliance Quality Assurance Division ASAHI INTECC CO., LTD.
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN November 25, 2022 Place, Date		

Table 1 Model of ASAHI PTCA Guide Wire

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

Table 3 Applied harmonized standards (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 A1:2020	Medical devices – Part1: Application of usability engineering to medical devices
EN ISO 10993-1: 2020 ISO 10993-1: 2018	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 A1: 2022 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: 2021	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: 2021 ISO 10993-12: 2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-18:2020 ISO 10993-18:2020 A1:2021	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process

Standard Reference	Title
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: 2020 ISO 11607-1: 2019	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: 2019	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1: 2018 A: 2021 ISO 11737-1: 2018 A: 2021	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2: 2020 ISO 11737-2: 2019	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 A11: 2021 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

制定・改訂履歴

Ver.	制定・改訂日	内容
1	June 2, 2009	・ 新規制定
2	January 6, 2010	・ Manufacturing Facility に ASAHI INTECC HANOI CO., LTD.を追加。
3	March 21, 2010	・ Authorized representatives in EU を Emergo に変更。
4	June 4, 2010	・ 最新の規格リストに更新。
5	September 9, 2010	・ ULTIMATEbros 3 を追加。
6	June 15, 2011	<ul style="list-style-type: none"> ・ 最新の規格リストに更新 ・ 認証機関の名称変更 ・ 新名称の追加
7	June 2, 2012	・ 最新の規格リストに更新
8	July 12, 2013	・ 最新の規格リストに更新
9	June 3, 2014	・ 最新の規格リストに更新
10	May 21, 2015	<ul style="list-style-type: none"> ・ 最新の規格リストに更新 ・ クラス分類の規則"Rule 7"を追加(Item 1 in page 1) ・ 認証機関の住所を追加(Item 2,3 in page 1)
11	June 27, 2016	・ 最新の規格リストに更新
12	August 9 , 2017	<ul style="list-style-type: none"> ・ 最新の規格リストに更新 ・ 製品名から「Neo's」を削除
13	November 18 , 2017	<ul style="list-style-type: none"> ・ 適用規格リストを最新に更新 ・ Emergo 住所変更
14	November 13, 2018	・ 適用規格リストを最新に更新
15	November 20, 2019	・ 適用規格リストを最新に更新
16	June 8, 2020	・ 最新の規格に更新
17	January 18, 2021	・ 最新の規格に更新

Ver.	制定・改訂日	内容
18	June 25, 2021	・ 最新の規格に更新
19	October 22, 2021	・ ISO 10993-18:2020 追加 ・ EN ISO 10993-18:2020 追加 ・ 最新の規格に更新 ・ 役職の変更 General Manager ⇒ Person responsible for regulatory compliance ・ ASAHI INTECC (THAILAND) CO., LTD.の住所を修正
20	June 9, 2022	・ 最新の規格に更新
21	September 14, 2022	・ 最新の規格に更新
22	November 25, 2022	・ 最終ロットの記載