

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) NEO'S PTCA Guide Wire
(Series) ASAHI PTCA GUIDE WIRE AG, AGH, and AGP series
(Model) Refer to Table 1
(Serial of Lot No.)
From 8404810031 to
Name, type or model, batch or serial number, possibly source and number of items

of Class

III
According to 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)

3. CE Marking of Conformity Certificate No. 2107788CE01
Issued by DEKRA Certification B. V. (Notified under No. 0344)

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
Molenstraat 15, 2513 BH, The Hague, The Netherlands

6. Applied harmonized standards, national standards or other normative documents Refer to Table 2 and Table 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
July 12, 2013
Place, Date



Yoshihiko Fukui,
Executive Director
Senior General Manager
Quality Assurance Division
ASAHI INTECC CO., LTD.

Table 1 Model of ASAHI PTCA GUIDE WIRE

Product No.	Product Name	Product No.	Product Name
12780-01 (AG141000)	ASAHI SOFT 180cm	14939-01 (AG141300)	ASAHI SOFT 300cm
12780-02 (AG141000J)	ASAHI SOFT 180cm J	14939-02 (AG141300J)	ASAHI SOFT 300cm J
12781-01 (AG141002)	ASAHI GRAND SLAM 180cm	14940-01 (AG141302)	ASAHI GRAND SLAM 300cm
12781-02 (AG141002J)	ASAHI GRAND SLAM 180cm J	14940-02 (AG141302J)	ASAHI GRAND SLAM 300cm J
12782-01 (AG142000)	ASAHI MEDIUM 180cm	14941-01 (AG142300)	ASAHI MEDIUM 300cm
- (AG142000J)	ASAHI MEDIUM 180cm J	- (AG142300J)	ASAHI MEDIUM 300cm J
12783-01 (AG143000)	ASAHI STANDARD 180cm	14942-01 (AG143300)	ASAHI STANDARD 300cm
- (AG143000J)	ASAHI STANDARD 180cm J	- (AG143300J)	ASAHI STANDARD 300cm J
12785-01 (AG145000)	ASAHI LIGHT 180cm	14944-01 (AG145300)	ASAHI LIGHT 300cm
12785-02 (AG145000J)	ASAHI LIGHT 180cm J	14944-02 (AG145300J)	ASAHI LIGHT 300cm J
12778-01 (AG14M050)	ASAHI MIRACLEbros 3 180cm	14937-01 (AG14M350)	ASAHI MIRACLEbros 3 300cm
- (AG14M050J)	ASAHI MIRACLEbros 3 180cm J	- (AG14M350J)	ASAHI MIRACLEbros 3 300cm J
12777-01 (AG14M045)	ASAHI MIRACLEbros 4.5 180cm	14936-01 (AG14M345)	ASAHI MIRACLEbros 4.5 300cm
- (AG14M045J)	ASAHI MIRACLEbros 4.5 180cm J	- (AG14M345J)	ASAHI MIRACLEbros 4.5 300cm J
12779-01 (AG14M060)	ASAHI MIRACLEbros 6 180cm	14938-01 (AG14M360)	ASAHI MIRACLEbros 6 300cm
- (AG14M060J)	ASAHI MIRACLEbros 6 180cm J	- (AG14M360J)	ASAHI MIRACLEbros 6 300cm J
82903-01 (AG14M070)	ASAHI MIRACLEbros 12 180cm	82903-02 (AG14M370)	ASAHI MIRACLEbros 12 300cm
- (AG14M070J)	ASAHI MIRACLEbros 12 180cm J	- (AG14M370J)	ASAHI MIRACLEbros 12 300cm J
12784-01 (AG143090)	ASAHI CONFIANZA 180cm	14943-01 (AG143390)	ASAHI CONFIANZA 300cm
- (AG143090J)	ASAHI CONFIANZA 180cm J	- (AG143390J)	ASAHI CONFIANZA 300cm J
20629-01 (AGH143090)	ASAHI CONFIANZA PRO 180cm	20629-02 (AGH143390)	ASAHI CONFIANZA PRO 300cm
- (AGH143090J)	ASAHI CONFIANZA PRO 180cm J	- (AGH143390J)	ASAHI CONFIANZA PRO 300cm J
82902-01 (AGH143091)	ASAHI CONFIANZA PRO 12 180cm	82902-02 (AGH143391)	ASAHI CONFIANZA PRO 12 300cm
- (AGH143091J)	ASAHI CONFIANZA PRO 12 180cm J	- (AGH143391J)	ASAHI CONFIANZA PRO 12 300cm J
12776-01 (AGH146000)	ASAHI PROWATER 180cm	14935-01 (AGH146300)	ASAHI PROWATER 300cm
12776-02 (AGH146000J)	ASAHI PROWATER 180cm J	14935-02 (AGH146300J)	ASAHI PROWATER 300cm J
82358-01 (AGH147000)	ASAHI PROWATERflex 180cm	82358-02 (AGH147300)	ASAHI PROWATERflex 300cm
82358-11 (AGH147000J)	ASAHI PROWATERflex 180cm J	82358-12 (AGH147300J)	ASAHI PROWATERflex 300cm J
82359-01 (AGP140000)	ASAHI FIELDER 180cm	82359-02 (AGP140300)	ASAHI FIELDER 300cm
82359-11 (AGP140000J)	ASAHI FIELDER 180cm J	82359-12 (AGP140300J)	ASAHI FIELDER 300cm J

Product No.	Product Name	Product No.	Product Name
1011895H (AGP140001)	ASAHI FIELDER FC 180cm	1011896H (AGP140301)	ASAHI FIELDER FC 300cm
1011895HJ (AGP140001J)	ASAHI FIELDER FC 180cm J	1011896HJ (AGP140301J)	ASAHI FIELDER FC 300cm J
AGP140002	ASAHI FIELDER XT 190cm	AGP140302	ASAHI FIELDER XT 300cm

Table 2 Applied harmonized standards (QA-Related Standards)

Standard Reference	Title
EN ISO 13485:2012 AC:2012 ISO 13485:2003 Cor1:2009	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EC Directive 93/42/EEC L 169 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 556-2: 2003	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- Part 2: Requirements for aseptically processed medical devices
EN ISO 15223-1: 2012 ISO 15223-1: 2012	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied –Part1: General requirements
EN 1041:2008	Terminology, symbols and information provided with medical devices - Information Supplied by the Manufacturer
EN ISO 10993-1: 2009 AC: 2010 ISO 10993-1: 2009 Cor1: 2010	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-2: 2006 ISO 10993-2: 2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements – Second Edition
EN ISO 10993-4: 2009 ISO 10993-4: 2002 Amd 1: 2006	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood AMENDMENT 1
EN ISO 10993-5: 2009 ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for cytotoxicity: <i>in vitro</i> methods
EN ISO 10993-7: 2008 AC:2009 ISO 10993-7: 2008 Cor1:2009	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10: 2010 ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Tests for irritation and sensitization

Standard Reference	Title
EN ISO 10993-11: 2009 ISO 10993-11: 2006	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 11070: 1999 ISO 11070: 1998	Sterile, single-use intravascular catheter introducers
EN ISO 11135-1:2007 ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1:Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-1: 2006 ISO11138-1: 2006	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2: 2009 ISO 11138-2: 2006	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1: 2009 ISO 11607-1: 2006	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems-First edition
EN ISO 11607-2: 2006 ISO 11607-2: 2006	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes-First edition
EN ISO 11737-1: 2006 AC:2009 ISO 11737-1: 2006 Cor 1: 2007	Sterilization of medical devices – Microbiological methods – Part 1: Estimation of population of microorganisms on products Corrigendum 1
EN ISO 11737-2: 2009 ISO 11737-2: 2009	Sterilization of medical devices – Microbiological methods -- Part 2: Tests of sterility performed in the validation 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 14161: 2009 ISO 14161: 2009	Sterilization of Health Care Products - Biological Indicators - Guidance for the Selection, Use and Interpretation of Results-First Edition
EN ISO 14644-1: 1999 ISO 14644-1: 1999	Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness-First Edition
EN ISO 14644-2: 2000 ISO 14644-2: 2000	Cleanrooms and Associated Controlled Environments - Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1-First Edition
EN ISO 14644-3: 2005 ISO 14644-3: 2005	Cleanrooms and associated controlled environments - Part 3: Test methods-First Edition
EN ISO 14698-1: 2003 ISO 14698-1: 2003	Cleanrooms and associated controlled environments Biocontamination control - Part 1: General principles and methods - First Edition
EN ISO 14698-2: 2003 AC: 2006 ISO 14698-2: 2003 Cor1: 2004	Cleanrooms and associated controlled environments Biocontamination control - Part 1: General principles and methods - First Edition
EN ISO 14971: 2012 ISO 14971: 2007	Medical device – Application of risk management to medical devices
MEDDEV. 2.12-1: 2013	GUIDELINES ON A MEDICAL DEVICE VIGILANCE SYSTEM
MEDDEV. 2.7.1: 2009	EVALUATION OF CLINICAL DATA: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
MEDDEV. 2.12-2: 2012	POST MARKET CLINICAL FOLLOW-UP STUDIES