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 Neurovascular Guide Wire

(Model)

WAIN-CKI-008-200	ASAHI CHIKAI 008
WAIN-CKI-200-BS	ASAHI CHIKAI black
WAIN-CKI-200-BA	ASAHI CHIKAI black
WAIN-CKI-18-200-BS	ASAHI CHIKAI black 18

(Serial of Lot No.)
From 141106A39A 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.: 2107788DE14
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

3. CE Marking of Conformity Certificate No.: 2107788CE16
Issued by: DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

4. Manufacturing Facility: 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 1 and Table 2

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
December 6 , 2018
Place, Date

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

Digitally signed by Grabazei Alexandru
Date: 2024.04.03 17:09:00 EEST
Reason: MoldSign Signature
Location: Moldova

Table 1: Applied harmonized standards (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 /Amd1:1998 /Amd2:2000 /Amd3:2002 /Amd4:2003 /Amd5:2007	Medical Devices Directive (2007)

Table 2: 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 Cor1:2017/Cor2:2017 ISO 15223-1: 2016 Cor1:2016/Cor2:2017	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied –Part1: General requirements
EN 1041:2008 Amd1:2013	Information Supplied by the Manufacturer with Medical Devices
EN 62366-1:2015 Cor:2016	Medical devices – Application of usability engineering to medical devices
EN 980:2008	Graphical Symbols for Use in the Labeling of Medical Devices

Standard Reference	Title
EN ISO 10993-1: 2009 AC:2010 ISO 10993-1: 2009 Cor1:2010	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 Cor1:2009	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 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 11070: 2014 ISO 11070: 2014	Sterile, single-use intravascular introducers, dilators and guidewires
EN ISO 11135: 2014 ISO 11135: 2014	Sterilization of health care products -Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices-First Edition
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 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-First edition
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-First edition
EN ISO 11737-1: 2006 AC: 2009 ISO 11737-1: 2006 Cor 1: 2007	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products Corrigendum 1

Standard Reference	Title
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: 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: 2005 **ISO 14644-3: 2005**	Cleanrooms and associated controlled environments - Part 3: Test methods-First Edition
EN ISO 14698-1: 2003 **Cor1:2003** **ISO 14698-1: 2003**	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: Evaluation and interpretation of biocontamination data
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 (ISO 14698-2:2003)
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: 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