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) Microcatheters
(Model) ASAHI Corsair (Refer to Table 1 in page 2/4)
(Serial of Lot No.) From 91006-10061 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.: 2107788DE09
Issued by: DEKRA Certification B.V. (Notified under No. 0344)
Arnhem, The Netherlands

3. CE Marking of Conformity Certificate No.: 2107788CE10
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

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 3/4 – 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
September 14, 2022
Place, Date

[redacted]

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

Table 1 Model of Corsair series

Product name 製品名	Model No. モデルナンバー	Description 詳細
ASAHI Corsair	CSW135-26N	ASAHI Corsair Microcatheter, 2.6 Fr, Straight, 135cm
	CSW150-26N	ASAHI Corsair Microcatheter, 2.6 Fr, Straight, 150cm

Table 2 Applied standards

Standard Reference	Title
1. QA-RELATED STANDARDS	
EN ISO 13485: 2016 A: 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)
2. PRODUCT-RELATED STANDARDS	
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 1041: 2008 A:2013	Information supplied by the manufacturer of medical devices
EN ISO 10555-1: 2013 C:2013/A:2017 ISO 10555-1: 2013 A:2017	Intravascular catheters – sterile and single-use catheters - Part1: General requirements
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
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

Standard Reference	Title
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 13868: 2002	Catheters - Test methods for kinking of single lumen catheters and medical tubing
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 C1: 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
EN ISO 15223-1: 2016 C1:2017/C2:2017 **ISO 15223-1: 2016 C:2016/C2:2017**	Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied –Part1: General requirements
EN ISO 80369-1:2018 **ISO 80369-1:2018**	Small-bore connectors for liquids and gases in healthcare applications- Part 1: General requirements
EN ISO 80369-7:2017 C:2017 **ISO 80369-7:2016**	Small-bore connectors for liquids and gases in healthcare applications- Part 7: Connectors for intravascular or hypodermic applications
EN ISO 80369-20: 2015 **ISO 80369-20: 2015**	Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods
EN 62366-1:2015 A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
MEDDEV 2.7/1: 2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
MEDDEV 2.12-1: 2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
MEDDEV 2.12-2: 2012	POST MARKET CLINICAL FOLLOW-UP STUDIES