



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) Double Lumen Catheter (RX/OTW)
(Model) SA145-33N ASAHI SASUKE
(Serial of Lot No.)
From 180720F041 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. 2107788DE22
Issued by DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

3. CE Marking of Conformity Certificate No. 2107788CE28
Issued by DEKRA Certification B. V. (Notified under No. 0344)
Arnhem, The Netherlands

4. Manufacturing Facility ASAHI INTECC (THAILAND) CO., LTD.
158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi
Amphur Muang, 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 1 and 2 in page 2/4-4/4

7. Conformity assessment procedure Based on Medical Devices Directive 93/42/EEC Annex II 3 and 4

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.

1. QA-Related Standards 品質関連の規格

Standard Reference 規格略号・番号	Title タイトル
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 製品関連の規格

Standard Reference 規格略号・番号	Title タイトル
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 62366-1:2015 C:2016	Medical devices – Application of usability engineering to medical devices
EN 20594-1:1993 AC:1996 A1:1997 ISO 594-1:1986	Conical Fittings with a 6%(Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part1: General Requirements
EN 1707:1996 ISO 594-2:1998	Conical Fittings with a 6%(Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Look Fittings
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 13868:2002	Catheters – Test Methods for Kinking of Single Lumen Catheters and Medical Tubing
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 ISO 10993-1: 2009 AC:2010 ISO 10993-1: 2009 AC: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

Standard Reference 規格略号・番号	Title タイトル
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 C1:2009/A1:2019	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 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: 2012 ISO 10993-12: 2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-17: 2009 ISO 10993-17: 2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18: 2020 ISO 10993-18: 2020	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 ISO11138-1: 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: 2017 ISO 11607-1: 2006 A: 2014	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: 2006 A: 2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1: 2018 C:2018 ISO 11737-1: 2018	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products

Standard Reference 規格略号・番号	Title タイトル
EN ISO 11737-2: 2009 ISO 11737-2: 2009	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 C1: 2004	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
EN ISO 14971: 2019 ISO 14971: 2019	Medical devices – Application of risk management to medical devices
MEDDEV. 2.12-1:2013	GUIDELINES ON A MEDICAL DEVICE VIGILANCE SYSTEM
MEDDEV. 2.12-2:2012	POST MARKET CLINICAL FOLLOW-UP STUDIES
MEDDEV.2.7/1: 2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

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-CD045 Ver.6				
October 22, 2021	-The title of the company representative was changed from "General Manager" to "Person responsible for regulatory compliance." -The address of ASAHI INTECC (THAILAND) CO., LTD. was corrected. <table border="1" data-bbox="440 909 1153 1155"> <tr> <td data-bbox="440 909 547 1014">Before</td> <td data-bbox="547 909 1153 1014">158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi Amphur Muang, Pathumthani 12000, Thailand</td> </tr> <tr> <td data-bbox="440 1014 547 1155">After</td> <td data-bbox="547 1014 1153 1155">158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi Amphur Muang Pathumthani, Pathumthani 12000, Thailand</td> </tr> </table> -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	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-CD045 Ver.7
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					
March 8, 2022	-The applicable standards were updated to the following: EN ISO 10993-12: 2021 ISO 10993-12: 2021 EN ISO 11737-1: 2018 A:2021 ISO 11737-1: 2018 A:2021	AMM-CD045 Ver.8				
June 9, 2022	-The applicable standards were updated to the following: EN ISO 10993-7: 2008 (+A1:2022) EN ISO 14971: 2019 A11:2021	AMM-CD045 Ver.9				
September 14, 2022	-The applicable standards were updated to the following: ISO 10993-10: 2021 ISO10993-18:2020 A1:2021	AMM-CD045 Ver.10				

Addendum to the original Declaration of Conformity (MDD)

Date of Change	Descriptions	Corresponding Version						
June 1, 2023	<p>-The applicable standards were updated to the following due to the wrong description:</p> <ul style="list-style-type: none"> EN ISO 10993-1: 2009 AC: 2010 ISO 10993-1: 2009 Cor1: 2010 EN ISO 10993-7: 2008 AC:2009 EN ISO 10993-18: 2009 ISO 10993-18: 2005 EN ISO 11607-1: 2017 ISO 11607-1: 2006 Amd1: 2014 ISO 11607-2: 2006 Amd1: 2014 <p>-As of January 31, 2023, the address of our EU Authorized Representative as listed on the original DoC has been changed.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Name of company</td> <td>Emergo Europe B.V.</td> </tr> <tr> <td>Old Address</td> <td>Prinsessegracht 20, 2514 AP The Hague, The Netherlands</td> </tr> <tr> <td>New Address</td> <td>Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands</td> </tr> </table>	Name of company	Emergo Europe B.V.	Old Address	Prinsessegracht 20, 2514 AP The Hague, The Netherlands	New Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands	AMM-CD045 Ver.11
Name of company	Emergo Europe B.V.							
Old Address	Prinsessegracht 20, 2514 AP The Hague, The Netherlands							
New Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands							
January 30, 2024	<p>-The applicable standards were updated to the following:</p> <ul style="list-style-type: none"> EN ISO 10993-2: 2022 ISO 10993-2: 2022 EN ISO 10993-10: 2023 <p>-ISO 10993-23:2021 and EN ISO 10993-23:2021 were added.</p>	NA						

Aichi, Japan, January 30, 2024

Place and date of issue



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