心脉医疗 Endovastec

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Declaration of Conformity

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Date: 25-03-2020

Declaration of Conformity

Manufacturer:	Shanghai MicroPort Endovascular MedTech Co., Ltd. Building #1, 3399 Kangxin Road, 201318 Shanghai, PEOPLE'S REPUBLIC OF CHINA
European Representative:	Paasheuvelweg 25, 1105BP Amsterdam, The Netherlands
Product Name:	Minos™ Sterile Abdominal Aortic Stent-Graft and Delivery System
Product Model:	Please find in Appendix I
GMDNS Code:	46777
Classification: (Annex IX of the MDD)	Class III Medical Device, Rule 8
Conformity Assessment Route:	Annex II, MDD 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices (Amended by 2007/47/EC). All supporting documentation is retained under the premises of the manufacturer.

Notified Body:	UDEM Uluslararasi Belgeiendirme A.S.
NB Identification number:	2292
(EC) Certificate:	M.2019.106.12584; M.2019.106.12584-1
Expire date of the Certificate:	27-05-2024
Place:	Shanghai, P. R. China
Date of Issue	12-09-2019
Signature:	Guocheng Jin Name: Guocheng Jin Position: Vice President of Quality & Regulatory

Appendix I: Product Model and Specifications

Minos has three models with the specifications shown in Table 1. Minos' models are classified into three types: Main Body Stent Graft System (CM), CUFF Stent Graft System (CC) and Limb Stent Graft System (CL).

Table 1 Model and Specifications of Minos™ Abdominal Aortic Stent-Graft and Delivery System

Model and Specifications of Main Body Stent Graft System	CM22-90	CM24-90	CM26-90	CM28-90	CM30-90	CM32-90	CM34-90
	CM22-100	CM24-100	CM26-100	CM28-100	CM30-100	CM32-100	CM34-100
	CM22-110	CM24-110	CM26-110	CM28-110	CM30-110	CM32-110	CM34-110
	CM22-120	CM24-120	CM26-120	CM28-120	CM30-120	CM32-120	CM34-120
	CM22-130	CM24-130	CM26-130	CM28-130	CM30-130	CM32-130	CM34-130
	CM22-140	CM24-140	CM26-140	CM28-140	CM30-140	CM32-140	CM34-140
Profile of the delivery system	14F			16F			
Working length of the delivery system	550mm						

Model and Specifications of CUFF Stent Graft System	CC22-40	CC24-40	CC26-40	CC28-40	CC30-40	CC32-40	CC34-40	CC36-40
Profile of the delivery system	16F							
Working length of the delivery system	550mm							

Model and Specifications of Limb Stent Graft System	CL10-80	CL13-80	CL16-80	CL18-80	CL20-80	CL22-80	CL24-80
	CL10-90	CL13-90	CL16-90	CL18-90	CL20-90	CL22-90	CL24-90
	CL10-100	CL13-100	CL16-100	CL18-100	CL20-100	CL22-100	CL24-100
	CL10-110	CL13-110	CL16-110	CL18-110	CL20-110	CL22-110	CL24-110
	CL10-120	CL13-120	CL16-120	CL18-120	CL20-120	CL22-120	CL24-120
	CL10-130	CL13-130	CL16-130	CL18-130	CL20-130	CL22-130	CL24-130
	CL10-140	CL13-140	CL16-140	CL18-140	CL20-140	CL22-140	CL24-140
Profile of the delivery system	12F						
Working length of the delivery system	610mm						

Appendix □: Applicable regulatory standards

No.	Standard
1	EN ISO 14630:2012 Non-active surgical implants - General requirements
2	EN ISO 25539-1:2017 Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses
3	EN ISO 10555-1:2013/A1:2017 Intravascular catheters - Sterile and single-use catheters- Part 1: General requirements - Amendment 1
4	EN 20594-1 1993/A1:1997 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
5	ISO 594-2:1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings
6	EN ISO 8536-4:2013/A1:2013 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
7	EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
8	EN ISO 10993-1:2009/AC:2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Technical Corrigendum 1
9	EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
10	EN ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
11	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
12	EN ISO 10993-6:2016 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
13	EN ISO 10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
14	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
15	EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
16	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
17	EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
18	EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
19	EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods

	- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
20	EN ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
21	EN ISO 11138-2:2017 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
22	EN ISO 11607-1:2017 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
23	EN ISO 11607-2:2017 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
24	EN ISO 780:2015 Packaging - Distribution packaging - Graphical symbols for handling and storage of packages
25	EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
26	EN 1041-2008/A1:2013Information supplied by the manufacturer of medical devices
27	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice
28	EN ISO 14644-1:2015 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
29	EN 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
30	EN ISO 14644-3:2005 Cleanrooms and associated controlled environments - Part 3: Test methods
31	EN ISO 14698-1:2003 Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
32	EN ISO 14698-2:2003+Cor1:2004 Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
33	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
34	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
35	EN 62366-1: 2015/COR 2015 Medical devices Part1:Applications of usability engineering to medical devices
36	European Pharmacopoeia EP 9.5

37	EN ISO 7198:2017 Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches