CHENGDU OCI MEDICAL DEVICES CO., LTD
No.2401, West Port Avenue, Southwest Airport Economic Development Zone,
ShuangliuDistrict, Chengdu, Sichuan Province, China.
Tel.: +86-28-67085899 Fax: +86-28-67085880

To whom it may concern

Manufacturer's Authorization

Date: January 10th, 2024

We, *Chengdu OCI Medical Devices Co., Ltd.*, located at No. 2401 West Port Avenue, Southwest Airport Economic Development Zone Shuangliu District, Chengdu, Sichuan Province, China, who are official manufacturers of OCI polyethersulfone hollow fiber hemodialyzer with model number is: OCI-HD14L; OCI-HD16L; OCI-HD18L, do hereby declare that

"ECHIPAMED-PLUS" SRL
str. Valea Trandafirilor 24 "B", of. 2-7
MD-2001, Chisinau
Republic of Moldova

is our official distributor and local representative for OCI polyethersulfone hollow fiber hemodialyzer with model number is: OCI-HD14L; OCI-HD16L; OCI-HD18L of Chengdu OCI Medical Devices Co., Ltd., in the territory of the Republic of Moldova.

We declare that above mentioned company is authorized to do registration, quote, sell, as well as to perform after sales service of OCI polyethersulfone hollow fiber hemodialyzer with model number is : OCI-HD14L; OCI-HD16L; OCI-HD18L manufactured by us.

We hereby extend our full warranty with respect to the goods offered by the us.

This authorization letter will remain valid until 10th January, 2025. It will be terminated by either party with 3 months' written notice.

Name: Hongjian Wang

Signature:

Title: Genral Manager

Chengdu OCI Medical Devices Co., Ltd.

CHENGDU OCI MEDICAL DEVICES CO., LTD 成都欧医疗器械有限公司 91012250960807

Digitally signed by Iurchevici Valeriu
Date: 2024.01.12 17:54:20 EET
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA mun. CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600077677

LOA-OCISS3LCYMD20240111EP

Certificate CN14/30418

The management system of

Chengdu OCI Medical Devices Co., Ltd.

No. 2401, West Port Avenue, Southwest Airport Economic Development Zone, Shuangliu District, Chengdu, Sichuan Province, 610299, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and Manufacture of Sterile Polyethersulfone Hollow Fiber Hemodialyzer, Sterile Hemodialysis Blood Tubing Sets and Sterile Arteriovenous Fistula Needle Sets

This certificate is valid from 24 March 2023 until 02 April 2026 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 02 April 2014

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

EC Certificate Full Quality Assurance System: Certificate CN19/41099

The management system of

Chengdu OCI Medical Devices Co., Ltd.

No.2401, West Port Avenue, Southwest Airport Economic Development Zone, Shuangliu District, Chengdu, Sichuan Province, 610299, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile Polyethersulfone Hollow Fiber Hemodialyzer,
Sterile Hemodialysis Blood Tubing Sets,
Sterile Arteriovenous Fistula Needle Sets

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 02 April 2014
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CN/SZX 49598

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

EC Declaration of Conformity

Manufacturer: Chengdu OCI Medical Devices Co., Ltd. (SRN: CN-MF-000009700)
Address: No.2401, West Port Avenue, Southwest Airport Economic Development Zone, Shuangliu District, Chengdu, Sichuan Province, China.
Tel.: +86-28-67085899 Fax: +86-28-67085880

European representative: Lepu Medical (Europe) Cooperatief U.A. (SRN: NL-AR-000000551)
Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
Tel: +31-515-573399 Fax: +31-515-760020

Product: Polyethersulfone Hollow Fiber Hemodialyzer
Specification(s): Refer to Annex 1
Classification: According to Annex IX, Rule 3 of the MDD 93/42/EEC, Polyethersulfone Hollow Fiber Hemodialyzer is in class IIb.
Conformity Assessment Route: Conformity Assessment Route: MDD 93/42/EEC, Annex II (excluding Section 4)
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices.

CE 1639

SGS Belgium NV
Certificate No.: CN19/41099
Issue date: Dec., 16th, 2019
Expiry date: May, 24th, 2024

All supporting documentation is retained under the premises of the manufacturer and Notified Body 1639, SGS Belgium NV, SGS House Noorderlaan 87 2030 Antwerp Belgium.

Name: Tu Yuping
Signature: TuYuping

Title: Person responsible for regulation compliance(PRRC)
Place: Chengdu, China
Date: Dec., 31th, 2022

GMDN CODE: 47072

Annex 1-Product specifications

Table 1 Product Specifications

Product Name	Business Name	Product Description	Specification	Model	Effective Surface Area(m^2)	Basic UDI-DI	UDI-DI
Polyether sulfone Hollow Fiber Hemodialyzer	Purifier® or OCI®	High-Flux Polyethersulfone Hollow Fiber Hemodialyzer	High Flux	OCI-HD150	1.5	PHFH001XS	6937909301508
				OCI-HD180	1.8	PHFH001XS	6937909301805
				OCI-HD200	2.0	PHFH001XS	6937909302000
		Low-Flux Polyethersulfone Hollow Fiber Hemodialyzer	Low Flux	OCI-HD14L	1.4	PHFH001XS	6937909300143
				OCI-HD16L	1.6	PHFH001XS	6937909300167
				OCI-HD18L	1.8	PHFH001XS	6937909300181
				OCI-HD20L	2.0	PHFH001XS	6937909300204
		Hollow Fiber Membrane Hemodialyzer	Middle Flux	OCI-HD130M	1.3	PHFH001XS	6937909305339
				OCI-HD140M	1.4	PHFH001XS	6937909305346
				OCI-HD150M	1.5	PHFH001XS	6937909305353
				OCI-HD160M	1.6	PHFH001XS	6937909305360
				OCI-HD170M	1.7	PHFH001XS	6937909305377
				OCI-HD180M	1.8	PHFH001XS	6937909305384
				OCI-HD190M	1.9	PHFH001XS	6937909305391
				OCI-HD200M	2.0	PHFH001XS	6937909305407
			High Flux	OCI-HD13M	1.3	PHFH001XS	6937909305131
				OCI-HD15M	1.5	PHFH001XS	6937909305155
				OCI-HD16M	1.6	PHFH001XS	6937909305162
				OCI-HD17M	1.7	PHFH001XS	6937909305179
				OCI-HD18M	1.8	PHFH001XS	6937909305186
				OCI-HD19M	1.9	PHFH001XS	6937909305193
				OCI-HD20M	2.0	PHFH001XS	6937909305209
				OCI-HD21M	2.1	PHFH001XS	6937909305216
				OCI-HD23M	2.3	PHFH001XS	6937909305230
				OCI-HD25M	2.5	PHFH001XS	6937909305254
		Hollow Fiber	Low Flux	OCI-HD110L	1.1	PHFH001XS	6937909307111

		Dialyzer		OCI-HD130L	1.3	PHFH001XS	6937909307135
				OCI-HD140L	1.4	PHFH001XS	6937909307142
				OCI-HD150L	1.5	PHFH001XS	6937909307159
				OCI-HD160L	1.6	PHFH001XS	6937909307166
				OCI-HD170L	1.7	PHFH001XS	6937909307173
				OCI-HD180L	1.8	PHFH001XS	6937909307180
				OCI-HD190L	1.9	PHFH001XS	6937909307197
				OCI-HD200L	2.0	PHFH001XS	6937909307203
				OCI-HD210L	2.1	PHFH001XS	6937909307210
				OCI-HD230L	2.3	PHFH001XS	6937909307234
		Hollow Fiber Hemodiafilter	Super High Flux	OCI-HF160	1.6	PHFH001XS	6937909302161
				OCI-HF170	1.7	PHFH001XS	6937909302178
				OCI-HF180	1.8	PHFH001XS	6937909302185
				OCI-HF200	2.0	PHFH001XS	6937909302208
				OCI-HF230	2.3	PHFH001XS	6937909302239
				OCI-HF250	2.5	PHFH001XS	6937909302253

NO.	Standard	Description	Issue date(available)	Compliance
1	EN ISO 8637-1:2020	Extracorporeal systems for blood purification - Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators	2020.04.15	Full
2	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2020.12.16	Full
3	EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014.10.15	Full
4	EN ISO 10993-4:2017	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood	2017.10.18	Full
5	EN ISO 10993-5:2009	Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity	2009.06.01	Full
6	EN ISO 10993-6:2016	Biological evaluation of medical devices-Part 6: Tests for local effects after implantation	2016.12.14	Full
7	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	2023.02.08	Full
8	EN ISO 10993-11:2018	Biological evaluation of medical devices-Part 11: Tests for systemic toxicity	2018.05.30	Part applicable and compliance
9	EN ISO 10993-12:2021	Biological evaluation of medical devices-Part 12: Sample preparation and reference materials	2021.06.16	Part applicable and compliance
10	EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	2009.04.29	Full
11	EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process	2020.05.27	Full
12	EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice	2020.08.19	Full
13	EN ISO 14971:2019	Medical devices-Application of risk management to medical devices	2019.12.18	Part applicable and compliance
14	EN ISO 14971:2019/A11:2021	Quality management and corresponding general aspects for medical devices	2021.12.08	Part applicable and compliance
15	ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971	2020.06	Part applicable and compliance
16	EN ISO 15223-1:2021	Medical devices-Symbols to be used with medical device labels, Labelling and information to be supplied-Part 1:General requirements	2021.09.29	Full
17	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2020.01.15	Full
18	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2020.01.15	Full
19	EN ISO 11137-1:2015	Sterilization of health care products-Radiation-part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2015.06.10	Full
20	EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 2: Revision to 4.3.4 and 11.2	2019.11.20	Full
21	EN ISO 11137-2:2015	Sterilization of health care products-Radiation-part 2: Establishing the sterilization dose	2015.06.10	Full
22	EN ISO 11137-3:2017	Sterilization of health care products-Radiation-part 3: Guidance on dosimetric aspects	2017.07.26	Full
23	EN ISO 14644-1:2015	Cleanrooms and associated controlled environments-Part 1: Classification of air cleanliness	2015.12.13	Full
24	EN ISO 14644-2:2015	Cleanrooms and associated controlled environments-Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	2015.12.13	Full
25	EN ISO 14644-3:2019	Cleanrooms and associated controlled environments-Part 3: Test methods	2019.10.16	Full
26	EN ISO 14644-4:2022	Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up	2022.12.07	Full
27	MEDDEV 2.7/1 Rev. 4	Clinical evaluation: Guide for manufacturers and notified bodies	2016.06	Full
28	MEDDEV 2.12/1 Rev.8	Guidelines on a medical devices vigilance system	2013.01	Full

29	MEDDEV 2.12/2 Rev.2	Post market clinical follow-up studies	2012.01	Full
30	IEC 62366-1:2015+AMD1:2020 CSV	Medical devices - Part 1: Application of usability engineering to medical devices	2020.06.17	Part applicable and compliance
31	IEC/TR 62366-2:2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	2016.04.27	Full
32	ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	2015.10.01	Full
33	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2021.12.15	Full
34	ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems	2016.04.01	Full
35	EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	2018.01.31	Full
36	EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1	2021.06.16	Full
37	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2020.05.13	Full

- Revision Table -

Rev. No.	Description of Change	Originator	Date
1/0	Firstly released.	Yu Huang	2015.12.08
2/0	Update according to latest regulations.	Yu Huang	2018.02.22
3/0	Update according to latest regulations.	Yuping Tu	2019.02.22
4/0	Add new models.	Lei Lei	2020.09.01
5/0	Update according to latest regulations.	Yuping Tu	2021.04.16
5/1	Add UDI	Lei Lei	2022.12.31