STATEMENT

Our company SWS HEMODIALYSIS CARE CO., LTD. located in No.1 Ciji Road, Liangjiang New District, Chongqing, China, we will export our products Hemodialysis equipment, and has obtained the copy of EC Certificate due to registration needs. See the attachment for the detailed certificate.

Hereby declare!

SWS MEDICAL
Science · Wellness · Safety ·

Address: No.1, Ciji Road, Liangjiang New District, Chongqing China
Post Code:401121/Tel:+86 15680862260 Fax:+86 23 6862 0310
E-mail: cao.yu@swskj.com
Website: www.swskj.com

DNV

Notified Body Confirmation Letter Reference: C651269

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

SWS Hemodialysis Care Co., Ltd.

No.1 Ciji Road, Liangjiang New District, Chongqing, 401123, China

SRN Number: CN-MF-000024516

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

Place and date:
Høvik, 2023.12.20

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Hemodialysis Equipment-SWS-4000 series Basic UDI-DI: 69557484SWS-4000DY Model: SWS-4000, SWS-4000A	IIb	NA	10000438818-PA-NA-CHN NB number: NB 2460
Hemodialysis Equipment-SWS-5000 series Basic UDI-DI: 69557484SWS-5000E7 Model: SWS-5000, SWS-5000A, SWS-5000B	IIb	NA	10000438818-PA-NA-CHN NB number: NB 2460
Hemodialysis Equipment-SWS-6000 series Basic UDI-DI: 69557484SWS-6000EE Model: SWS-6000, SWS-6000A	IIb	NA	10000438818-PA-NA-CHN NB number: NB 2460

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/12/20	C651269	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.

本附加证明书仅证明公文书上的签名、签署人签名时的身份，需要时可证明公文书上的印鉴属实。附加证明书不对公文书内容予以证明。
This Apostille only certifies the authenticity of the signature, the capacity of the person who has signed the public document and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued.
Visit https://consular.mfa.gov.cn/VERIFY/ and scan the QR code to verify the issuance of this Apostille.

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附加证明书
APOSTILLE

（1961年10月5日海牙公约）
(Convention de La Haye du 5 octobre 1961)

1. 文书出具国：
Country: 中华人民共和国
People's Republic of China

本公文书 This public document

2. 签署人
has been signed by 孙嘉
Sun Jia

3. 签署人身份
acting in the capacity of 签证员
Authorized Official

4. 印鉴名称
bears the seal/stamp of 中国国际贸易促进委员会
China Council for the Promotion of International Trade

证明 Certified

5. 签发地
at 北京
Beijing

6. 签发日期
the 2024年07月16日
July 16,2024

7. 签发人
by 孙仁安，参赞/ Sun Renan，Counsellor
外交部领事司
Department of Consular Affairs of the Ministry of Foreign Affairs

8. 附加证明书编号
No 认字第240000308895号

9. 签发机关印鉴：
Seal/Stamp:

10. 签名：
Signature: