EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144433 0001

Report No.: 17054024 008

Manufacturer:
Shenzhen Upnmed Equipment
Co., Ltd.
4th Floor, Building #1 East
Huihuang Industrial Area
Xitian Community, Gongming Town
Guangming New District
Shenzhen
518107 Guangdong
China

Products:
Oximeter Probes

Replaces Approval, Registration No.: HD 60126823 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-02

Date: 2019-12-02

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Ermicev Alexandr
Date: 2026.05.20 16:29:06 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

Letter of Confirmation #1

14 May 2024

FI24/07195P0

Shenzhen UpnMed Equipment Co.,ltd
No.301,Building #41st ,The 3rd Industrial Zone,
Xitian Community, Gongming Street,
Guangming District，Shenzhen,
China

Notified Body Letter of Confirmation

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, SGS Fimko Ltd, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0598 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:

Shenzhen UpnMed Equipment Co.,ltd
No.301,Building #41st ,The 3rd Industrial Zone,
Xitian Community, Gongming Street,
Guangming District，Shenzhen,
China

SRN: CN-MF-000019212

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 90/385/EEC (AIMDD) or 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/AIMDD 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:

- 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)

On behalf of the Notified Body,

Helsinki, 14 May 2024

Seppo Vahasalo, Notified Body Manager

SGS Fimko Ltd

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 or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SpO2 Sensor Models: U401-A, U401-B, U401-C, U401-D	Class IIb	N/A	HD 60144433 0001 NB 0197

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 or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Certificate of Registration

This is to certify that the Quality Management System of

Shenzhen UpnMed Equipment Co., Ltd

Unified Social Credit Code: **914403006610255394**

Operation Address: **No.301, Building #41st, The 3rd Industrial Zone, Xitian Community, Gongming Street, Guangming District, Shenzhen, Guangdong, China**

Registered Address: **No.301, Building #41st, The 3rd Industrial Zone, Xitian Community, Gongming Street, Guangming District, Shenzhen, Guangdong, China**

applicable to

Design, production and sales of SpO2 Sensor, Blood Pressure Cuffs, ECG Cables and Disposable SpO2 Sensor (within the scope of licensed qualifications)

has been assessed and registered by NQA against the provisions of

ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number: **134778**

Issue Date: **18 February 2025**

Valid Until: **18 February 2028**

UKAS MANAGEMENT SYSTEMS

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The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.
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This certificate is the property of NQA and must be returned on request.
Shanghai NQA Certification Co., Ltd. Address: Room 2201, 958 Lujiazui Ring Road, China (Shanghai) Pilot Free Trade Zone.