EU Quality Management System Certificate FI26/1008025

The quality management system of

Shenzhen Upnmed Equipment Co.,Ltd

No.301, Building #41st, The 3rd Industrial Zone, Xitian Community, Gongming Street, Guangming District, Shenzhen, 518106, China SRN: CN-MF-000019212

has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745 Annex IX (I and III)

for the following:
SpO2 sensors

Issue 1
Previous certificate's number and issue: N/A
Change in between this certificate and the previous one: N/A

The devices covered, their risk classifications, codes applied, identification details, intended purposes, standards and common specifications followed, conditions or limitations, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 2 June 2026 until 1 June 2029 and remains valid subject to satisfactory surveillance audits.
Certified since 2 June 2026
Certified activities performed by additional sites are listed on the subsequent pages.

Authorised by
Jani Högman, Certifier

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Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland
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Shenzhen Upnmed Equipment Co.,Ltd

Regulation (EU) 2017/745 Annex IX (I and III)

Issue 1
Sites
Shenzhen Upnmed Equipment Co.,Ltd No.301, Building #41st, The 3rd Industrial Zone, Xitian Community, Gongming Street, Guangming District, Shenzhen, 518106, China Design, production, purchase, sale, admin, and warehouse

Shenzhen Upnmed Equipment Co.,Ltd

Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 1

Risk classes, codes, identification, and other relevant details of the certified devices:

Risk class IIb
MDA 0203, MDT 2010, MDT 2011
EMDN C900301 PULSE OXIMETER SENSORS
SpO2 sensor, Basic UDI-DI: 697040488U401FJ
models: U401-A, U401-B, U401-C, U401-D
intended use: This SpO2 Sensor is used with the Mindray patient monitor PM8000 for the continuous noninvasive monitoring and spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR, measured by an SpO2 sensor), for use with adult and pediatric patients.

The certification decision is based on the following:

Report Identification and Date:
Audit report: MDR-2021_Shenzhen Upnmed_2026V1_FPMDREG3019 - MD Audit Report Ver H dated 2026-05-14
Technical documentation assessment reports: MDR-2021_Shenzhen Upnmed_2024V1_FPMDREG3020 - MDR Technical Documentation Assessment Report Ver H Rev.1.0 dated 2026-04-08

Applied Standards / Common specifications:
EN ISO 13485:2016 + A11/2021, EN ISO 14971:2019 + A11/2021, EN ISO 15223-1:2021, references to other relevant CS and harmonized standards are in the reports

Conditions for or limitation to the validity of the certificate:
N/A

EU Authorised Representative:
NL-AR-000010445, R Sight B.V., 47 Roald Dahllaan, 5629 MC, Eindhoven, Netherlands