EU Quality Management System Certificate FI23/1008003

The management system of

Shenzhen SunnyGrand Healthcare Technology Co., Ltd.

Room 801, 802, 803, 805 and 810, Building 5,
Nam Tai Inno Park, Tangwei Community, Fenghuang Street,
Guangming District, Shenzhen City, Guangdong Province, 518107
P.R.China
SRN: CN-MF-000017209

has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

For the following products:
Respiratory High-flow Therapy Devices and accessories, and Sleep Apnoea Breathing Therapy Devices and accessories

Previous certificate number: FI25/1008003, Issue 2
Change in between this certificate and previous one: Correction of the certificate number
Devices covered, risk classification, conditions or limitations, as well as audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 17 April 2025 until 23 October 2028 and remains valid subject to satisfactory surveillance audits.
Issue 3 Certified since 24 October 2023
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Jani Högman, Certifier

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FINAS
Finnish Accreditation Service
S009 (EN ISO/IEC 17021-1)

Shenzhen SunnyGrand Healthcare Technology Co., Ltd.

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Issue 3
Sites
Main site Room 801, 802, 803, 805 and 810 Building 5, Nam Tai Inno Park, Tangwei Community, Fenghuang Street, Guangming District, Shenzhen City, Guangdong Province, 518107 P.R.China
Manufacturing site Room 801, 802, 803, 805, 810 and 709, Building 5, Nam Tai Inno Park, Tangwei Community, Fenghuang Street, Guangming District, Shenzhen City, Guangdong Province, 518107 P.R.China

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Attachment 1 of Issue 3

Device or Device Group, EMDN Code	Risk Class	Identification Details
EMDN: R0602 Humidification Systems	IIa	Respiratory High-flow Therapy Device Model: NatrFlow 40H, NatrFlow 50H, NatrFlow 60A, NatrFlow 70A, NatrFlow 70P, NatrFlow 80A, NatrFlow 80P Accessories: Mask, water chamber, heated breathing tube and trolley
EMDN: Q030102 Antisnoring and Obstructive Sleep apnea Devices	IIa	Sleep Apnoea Breathing Therapy Device (CPAP), model: NatrMeet 20C, NatrMeet 20A, NatrSleep 20C, NatrSleep 20A, NatrSleep 20A Sweet, NatrMeet 20C Plus, NatrMeet 20A Plus, NatrSleep 20C Plus, NatrSleep 20A Plus, NatrSleep 20A Sweet Plus. Sleep Apnoea Breathing Therapy Device (BiPAP), model: NatrSleep 20S_Auto, NatrSleep 25S_Auto, NatrSleep 20S, NatrSleep 25S, NatrRes 25ST, NatrRes 25ST+, NatrRes 25V, NatrRes 25Vp, NatrRes SVAP, NatrRes 30ST, NatrRes 30ST+, NatrRes 30V, NatrRes 30Vp, NatrRes SVAP Pro, NatrRes 30 Premium, NatrSleep 20S_Auto Plus, NatrSleep 25S_Auto Plus, NatrSleep 20S Plus, NatrSleep 25S Plus, NatrRes 25ST Plus, NatrRes 25ST+ Plus, NatrRes 25V Plus, NatrRes 25Vp Plus, NatrRes SVAP Plus, NatrRes 30ST Plus, NatrRes 30ST+ Plus, NatrRes 30V Plus, NatrRes 30Vp Plus, NatrRes SVAP Pro Plus, NatrRes 30 Premium S Accessories: Mask, water chamber, breathing tube, heated breathing tube, trolley and SunnyMatrix Health Management System.
EMDN: R0301010201 CPAP mask	IIa	Full Face Mask This accessory is only intended for use with Sunny Grand's Sleep Apnoea Breathing Therapy Devices and Respiratory High-flow Therapy Devices. Nasal Mask and Nasal Pillow Mask These accessories are only intended for use with Sunny Grand's Sleep Apnoea Breathing Therapy Devices.
EMDN: R020104 CPAP AND NIV BREATHING CIRCUITS	IIa	Breathing tube This accessory is only intended for use with SunnyGrand's Sleep Apnoea Breathing Therapy Devices. Heated breathing tube This accessory is only intended for use with SunnyGrand's Sleep Apnoea Breathing Therapy Devices and Respiratory High-flow Therapy Devices
EMDN: V92 MEDICAL DEVICE SOFTWARE-NOT INCLUDED IN OTHER CLASSES	IIa	SunnyMatrix Health Management System Only intended for use with SunnyGrand's Sleep Apnoea Breathing Therapy Devices include: SunnyCenter Cloud Platform, model SunnyCenter; SunnyCare Healthcare Manager Application, model SunnyCare; SunnyData Analysis Software, model SunnyData

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The certification decision is based on the following:

Report Identification and Date
Medical Device Certification Audit Report, MDR-2021_Shenzhen SunnyGrand_2024V2_FPMDREG3019 - MD Audit Report Ver F_Rev.1, dated 2024-09-13 Technical Documentation Assessment report,MDR-2021_SunnyGrand_2023V2_FPMDREG3020 - MDR Technical Documentation Assessment Report Ver G_Rev.1.1, dated 2025-01-03.

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

EU Authorised Representative
Wellkang Ltd Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland SRN: XI-AR-000001836