EU Quality Management System Certificate FI24/1008005

The management system of

Shenzhen Jumper Medical Equipment Co., Ltd

D Building, No. 71, Xintian Road, Fuyong Street, Baoan,
Shenzhen, Guangdong 518103,
China
SRN: CN-MF-000014343

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
TENS Therapy Devices, Electronic Blood Pressure Monitors, Pulse Oximeters, Infrared Thermometers, Fetal Dopplers and Fetal Monitors.

Certification is based on decision FI24/08140P0.
Previous certificate number: N/A
Change in between this certificate and previous one: N/A
Devices covered, risk classification, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 22 February 2024 until 21 February 2029 and remains valid subject to satisfactory surveillance audits.
Issue 1 Certified since 22 February 2024
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Seppo Vahasalo, NB Manager

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

Shenzhen Jumper Medical Equipment Co., Ltd

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

Issue 1
Sites
Main site: D Building, No.71, Xintian Road, Fuyong Street, Baoan, Shenzhen, Guangdong 518103, China Administration, Design and development, Manufacturing, Warehouse, Sales

Shenzhen Jumper Medical Equipment Co., Ltd

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

Attachment 1 of Issue 1

Device or Device Group, EMDN Code	Risk Class	Identification Details
EMDN Z12062899	IIa	TENS Therapy Device Model: JPD-ES100, JPD-ES200, JPD-ES210, JPD-ES220
EMDN Z1203020501	IIa	Electronic Blood Pressure Monitor Model: JPD-HA100, JPD-HA120, JPD-HA101, JPD-HA121, JPD-HA200, JPD-HA210, JPD-HA300, JPD-HA200C, JPD-HA201C, HWA10, HWA11, HWA20, HWA21, JPD-HW100A.
EMDN V0301010202	IIa	Infrared Thermometer Model: JPD-FR100+, JPD-FR300, JPD-FR301, JPD-FR302, JPD-FR400, JPD-FR401, JPD-FR403, JPD-FR409, JPD-FR409-BT, JPD-FR410, JPD-FR416, JPD-FR418, JPD-FR202, JPD-FR203, JPD-FR204, JPD-FR205, JPD-FR304, JPD-FR415.
EMDN Z12080103	IIa	Fetal Doppler: Model: JPD-100S, JPD-100S(mini), JPD-100S+, JPD-100S4, JPD-100S5, JPD-100S9, JPD-200S, JPD-100A, JPD-100A2, JPD-100B, JPD-100B2, JPD-100B3, JPD-100B4, JPD-100B+, JPD-100E, JPD-100E2, JPD-100E+, JPD-100S6, JPD-100S6+, JPD-100S6-2, JPD-200C, JPD-200C+.
EMDN: Z12080101	IIa	Fetal Monitor: Model: JPD-300P, JPD-300Pa, JPD-300Pb, JPD-300E.
EMDN Z1203020408	IIa	Pulse Oximeter Model: JPD-500A, JPD-500B, JPD-500C, JPD-500D, JPD-510D, JPD-500E, JPD-510E, JPD-500F, JPD-501F, JPD-502F, JPD-500G, JPD-501G, JPD-502G, JPD-500H, JPD-500I, JPD-510I.

The certification decision is based on the following:

Report Identification and Date
Audit report: MDR-2007 2023V1 FPMDREG3019 - MD Audit Report Ver E_Rev.4, dated 2024-02-22. TDA reports: MDR-2007_Shenzhen Jumper_JP-HA_FPMDREG3020 - MDR Technical Documentation Assessment Report Ver D_Rev.2 dated 2023-12-13, MDR-2007_Shenzhen Jumper_JP-SP_FPMDREG3020 - MDR Technical Documentation Assessment Report Ver D_Rev.2, dated 2023-12-13, MDR-2007_Shenzhen Jumper_JP-ES_FPMDREG3020 - MDR Technical Documentation Assessment Report Ver D_Rev.3, dated 2023-12-13.
Conditions for or limitation to the validity of the certificate
N/A

EU Authorised Representative
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