



Management Systems Certification Body
Institut pro testování a certifikaci, a.s.
trida Tomase Bati 299, Louky, 763 02 Zlin, Czech Republic
www.itczlin.cz

CERTIFICATE

No. 24 0089 SJ/a

We confirm on the basis of a performed audit that company

SPM Medicare Pvt. Ltd.

B-40, Phase II, Noida, Gautam Buddha Nagar, Uttar Pradesh - 201305, India

Company Reg. No.: U33110DL2014PTC269667

(a list of certified workplaces is contained in Annex which is inseparable part of this Certificate)

**has implemented and documented a functional quality management system
in compliance with the requirements of the standard**

EN ISO 13485:2016

Covering the following activities:

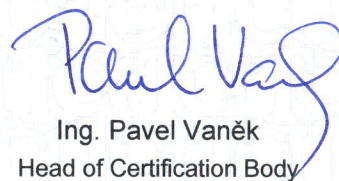
Scope of activities that the certificate applies to is contained in Annex which forms
an inseparable part of this Certificate.

The Certificate is issued on the basis of the results mentioned in Audit Report No.
243408149/2025. The Certificate validity is conditioned by positive results of surveillance audits,
which the certified company committed to undergo.

During use of the Certificate the Certificate Holder undertakes to follow the Rules of Use of the Certificate.
This document is publicly available on www.itczlin.cz



Date of Issue: 10. 11. 2025
Valid until: 13. 11. 2027


Ing. Pavel Vaněk
Head of Certification Body



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ANNEX TO CERTIFICATE

No. 24 0089 SJ/a

Issued for the company

SPM Medicare Pvt. Ltd.

B-40, Phase II, Noida, Gautam Buddha Nagar, Uttar Pradesh - 201305, India
Company Reg. No.: U33110DL2014PTC269667

List of certified workplaces:

Unit I: B-40, Phase II, Noida, Gautam Buddha Nagar, Uttar Pradesh - 201305, India

Unit III: Industrial Building Plot No. 26, Sector 158, Noida, Gautam Buddha Nagar,
Uttar Pradesh - 201305, India

Scope of activities:

Design, Development, Manufacturing & Supply of Sterile/ Non Sterile Medical devices covering Insulin Syringe; IV Cannula (with/without safety feature; with/without closed system with extension line); IV Infusion Set; Vial Adaptor Access Device; Hypodermic Syringe (with/without AD-RUP feature; with/without needle; with/without Sharp Injury Protection (SIP) Needle; with/without Retractable (RUP) features); Safety Needle; Flush Syringe (Prefilled 0.9% saline solution); Prefilled Sodium Citrate Flush Syringe; Prefilled Heparin Flush Syringe; Prefilled Syringe with sterile 10% Glycerin; Prefilled Syringe with sterile Water; Blood Transfusion Set (BT Set); In-Line Arterial Blood Sampling Set/Kit (with/without bubble remover); Oral Dispensing Syringe; Soft Tissue Trephine (Disposable Circumcision Stapler); Extension Line; 3-Way Stopcock (with/without Extension Line); IV Flow Regulator; Titanium Ligating Clips; Measured Volume IV Set; Trocar (Disposable); Alcohol Swab; Surgical Drape & Drape Accessories; Surgical Gown; Ortho Soft Goods

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Annex is an integral part of this Certificate and must not be used on its own.