



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. 22 0055 SJ/a

We confirm on the basis of a performed audit that company

Iscon Surgicals Limited

B-70, Marudhara Industrial Area, Phase-II, Basni, Jodhpur - 342005, Rajasthan, India

Company Reg. No.: 8602651572

Head Office and Factory: B-70, Marudhara Industrial Area, Phase-II, Basni, Jodhpur - 342005, Rajasthan, India

Factory: 22/4, Heavy Industrial Area, Jodhpur - 342003, Rajasthan, India

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. 243407787/2023. 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: 14. 11. 2023

Valid until: 21. 10. 2025

Date of the first certification awarding: 21. 10. 2013

A handwritten signature in blue ink that reads 'Pavel Vaněk'.

Ing. Pavel Vaněk
Head of Certification Body



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ANNEX TO CERTIFICATE

No. 22 0055 SJ/a

Issued for the company

Iscon Surgicals Limited

B-70, Marudhara Industrial Area, Phase-II, Basni, Jodhpur - 342005, Rajasthan, India


Company Reg. No.: 8602651572

Scope of activities:

Manufacture and Sale of Sterile and Non-Sterile Hypodermic Needles, Safety Needles, Pen Needles, Hypodermic Syringes with & without needle (Luer Lock, Luer slip), Auto Disable/RUP Syringes, Safety Syringes, Insulin Syringes, Tuberculin Syringes, Feeding Syringes, Catheter Tip Syringes, Spinal Needles with & without introducer, Epidural Needles, Special Purpose Needles & Cannulae, Suture Needles, Surgical Mesh, Infusion Set, Micro-Drip Set, Burret Set, Scalp Vein sets, Safety Scalp Vein Sets, Blood Transfusion Sets, 2/3 Way Stop Cock, Extension Line, IV-Cannula, Nelaton Catheter, Foley's Catheter, Male External Catheter, Female Catheter, Rectal Catheter, Urethral Catheter, Suction Catheter, Endotracheal Tube, Nasopharyngeal Airways, Catheter Mount, Bain Circuit, Ventilator Circuit, Epidural Catheter, Trechostomy Tube, Laryngeal Mask, Oxygen Mask, High Concentration Mask, Nasal Cannula, Nebulizer Mask, Ambu Bag, Urine Bag, Umbilical Cord Clamp, Huber Needle, Biopsy Needles, Bone Marrow Biopsy Needles, Biopsy Gun, Drainage Kits, Ryle's Tube, Stomach Tube, Levin's Tube, Feeding Tube, Umbilical Catheter, Yankauer Suction Set, Karman Cannula, Mucus Extractor, CVC Kit, Epidural Kit, Vacutainer Tube, Veress Needles, Liposuction Needles, Dental Needles, Blood Collection Needles/ Vacutainer Needles, Eye Testing Diagnostic Strips, Fluoresceine Strips, Schirmer Strips, Rose Bengal Strips, Lissamine Green Strips, Ophthalmic Instruments, Ophthalmic Cannula, Ophthalmic Blades, Trephines, Trocars, Spears, Lacrimal Intubation Sets/ DCR Sets, Bi Manual Handles, Swabs & Eye Shields

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Ing. Pavel Vaněk
Head of Certification Body

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