



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

## Iscon Surgicals Limited

B-70, MIA, Phase-II, Basni  
Jodhpur, Rajasthan 342005  
India

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

## Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

HYPODERMIC SYRINGES WITH OR WITHOUT NEEDLE according to annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	544098 MR2
Certificate unique ID	170756560
Effective date	2020-12-07
Expiry date	2024-05-26
Frankfurt am Main	2020-12-07

## DQS Medizinprodukte GmbH

Sigrid Uhlemann  
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Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



## Annex to certificate

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Device Family	Device	Class
HYPODERMIC SYRINGES WITH OR WITHOUT NEEDLE	STERILE HYPODERMIC SYRINGES WITH NEEDLE ATTACHED FOR SINGLE USE	IIa
	STERILE HYPODERMIC SYRINGES FOR SINGLE USE	
	STERILE SINGLE USE SYRINGE, WITH NEEDLE FOR INSULIN	
	TUBERCULIN SYRINGE	
	STERILE AUTO DISABLE SYRINGES FOR SINGLE USE	
	STERILE HYPODERMIC NEEDLE FOR SINGLE USE	





**Management Systems Certification Body**  
**Institute for Testing and Certification, Inc.**  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic  
[www.itczlin.cz](http://www.itczlin.cz)

# CERTIFICATE

**No. 19 0065 SJ**

We confirm on the basis of a performed audit that company

## **Iscon Surgicals Limited**

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

**Factory:** 22/4, Heavy Industrial Area, Jodhpur - 342003, Rajasthan, India  
Company Reg. No.: 8602651572

**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:

Manufacture and Sale of Sterile and Non-sterile Hypodermic Needles, Hypodermic Syringes, Insulin Syringes, Tuberculin Syringes, Syringes with Needle Attached, Auto Disable Syringes, Anesthesia Needle, Biopsy Needle, Bone Marrow Needle, Special Purpose Needle & Cannulae, Ophthalmic Cannulae, Ophthalmic Instruments, Perfusion Sets, Infusion Sets, Ophthalmic Blades, Suture Needles and Surgical Mesh

The Certificate is issued on the basis of the results mentioned in Audit Report No. 233404823/2019. 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](http://www.itczlin.cz)



Date of Issue: 21. 10. 2019  
Valid until: 21. 10. 2022

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

  
Ing. Pavel Vaněk  
Head of Certification Body