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
Managing Director

Dr. Thomas Feldmann
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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 544098 MR2
Certificate unique ID: 170756560
Effective date: 2020-12-07

Iscon Surgicals Limited

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

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	

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ISCON SURGICALS Ltd.

Plot No. B – 70,

MIA, Phase – II, Basni,

Jodhpur, Rajasthan - 342005, India

2024-05-24

Confirmation of receipt of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

To whom it may concern,

This letter confirms that DQS India (Deutsch Quality Systems (India) Private Limited) has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR. The application has been forwarded to our partner organization, DQS Medizinprodukte GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO. The application has been submitted for review to the NB prior to 26th of May 2024 for the following manufacturer:

ISCON SURGICALS Ltd.

Plot No. B – 70,

MIA, Phase – II, Basni,

Jodhpur, Rajasthan - 342005, India

SRN Number: IN-MF-000009761

The devices covered by the formal application above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received by DQS India and forwarded to DQS Medizinprodukte GmbH and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive (MDD). In terms of this letter this means that DQS India received either a signed agreement for continuation of MDD surveillance activities from DQS

Medizinprodukte GmbH, or a transfer agreement for surveillance of MDD legacy devices from DQS Medizinprodukte GmbH and the outgoing NB. Table 2 identifies the devices for which an MDR application has been received, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

The transition timelines that apply to the devices covered by this letter, from the perspective of DQS India, which are subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The intention of this letter is to confirm that no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3. For the transition timelines shown above to apply after 26 September 2024, the notified body and the manufacturer have to sign a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

You can contact DQS India if further information is required, also if it is required by DQS Medizinprodukte GmbH.

On behalf of DQS India

Kalaiselvan K
Regulatory Affairs Manager

DQS India
Deutsch Quality Systems (India) Private Limited
Managing Director & CEO
Dr. Murugan Kandasamy

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IEC : 0709000014
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GSTIN: 29AAACU9924E1Z3
MSME (Udyog Aadhar)
Regn. No.: KR03E0036364

DQS IS A MEMBER OF IQNET

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Hypodermic Syringes with or without Needle	Class IIa	N/A or Identification of the corresponding device under MDD/AIMDD	Cert # 544098 MR2 NB# 0297

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-24	50253811CL-01	Initial issue