[redacted]

EU Technical Documentation Assessment Certificate

This is to certify that the company

FRANCE CHIRURGIE INSTRUMENTATION SAS (FCI S.A.S.)

20-22 rue Louis Armand
75015 Paris
France

SRN: FR-MF-000000463

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Certificate registration no.	31624812 MDR2017P
Certificate ID	1000183481
Effective date	2024-06-27
Expiry date	2029-06-26
Frankfurt am Main,	2024-06-27

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de BS-MDR-094

DQS Medizinprodukte GmbH

[redacted]

Sigrid Uhlemann Managing Director	Michael Bothe Head of Certification Body (active medical devices)	Szymon Kurdyn Head of Certification Body (non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

420.92 Version 6.0

[redacted]

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: FR-MF-000000463
Certificate ID: 1000183481

Device categories and variants covered by this certificate:

Device category:	**MDN 1104 - Non-active soft tissue and other implants**
Product name:	BIOCERAMIC ORBITAL IMPLANTS
Models:	n/a
Risk classification:	IIb
Basic-UDI-DI:	3700773702358Z
Intended purpose:	The BIOCERAMIC ORBITAL IMPLANTS are designed to fill the orbital cavity.

Examinations and tests performed:
549168_A212776 dated 2024-06-12

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	n/a	n/a	n/a

This annex is only valid in connection with the above-mentioned certificate.

[redacted]

Déclaration CE de Conformité
EC Declaration of Conformity

Nous,

We,

FRANCE CHIRURGIE INSTRUMENTATION SAS (FCI S.A.S.)
20-22, rue Louis Armand
75015 PARIS, France

déclarons sous notre seule responsabilité que les dispositifs médicaux figurant sur l'addendum n°1 satisfont aux exigences de la Directive Européenne 93/42/CEE, conformément aux exigences essentielles de l'annexe I de la Directive Européenne 93/42/CEE et, en particulier, satisfont aux dispositions applicables du livre V bis du Code français de la Santé Publique et des arrêtés pris pour leur application.

hereby declare under our own responsibility that the medical devices listed on the attached addendum n°1 satisfy the requirements of the European Directive 93/42/EEC, conform to the essential requirements of the Annex I of the European Directive 93/42/EEC and, in particular, meet all applicable provisions of the book V bis of the French Health national regulation and the orders issued for their implementation.

La liste de l'addendum n°1 ci-joint indique, pour chaque dispositif médical sa classe suivant les règles de classification de l'Annexe IX de la Directive Européenne 93/42/CEE, la procédure d'évaluation de la conformité suivant l'article 11 de la Directive Européenne 93/42/CEE. Le Système de Management de la Qualité de FCI S.A.S. est certifié selon les normes NF EN ISO 13485 : 2016 et ISO 13485: 2016.

The attached addendum n°1 indicates, for each medical device, its class according to rules of Annex IX of the European Directive 93/42/EEC, the conformity assessment route according to article 11 of the European Directive 93/42/EEC). FCI S.A.S's. Quality Management System is certified against NF EN ISO 13485: 2016 and ISO 13485: 2016 standards.

De plus nous déclarons sous notre seule responsabilité que les dispositifs suivants (classe Is) sont fabriqués conformément à la documentation technique.

Furthermore, we declare under our sole responsibility that the following devices (class Is) are manufactured in accordance with their technical documentation.

De plus, nous déclarons sous notre seule responsabilité, suivant les règles de l'article 12 de la Directive Européenne 93/42/CEE et concernant les systèmes de plusieurs dispositifs médicaux portant le marquage CE et listés dans l'addendum n°2 :
- avoir vérifié la compatibilité réciproque des dispositifs, conformément aux instructions des fabricants et que ce réassemblage a été réalisé en suivant ces instructions,
- et avoir effectué l'emballage du système et fourni aux utilisateurs des informations pertinentes qui reprennent les instructions pertinentes des fabricants,
- et que toutes ces activités sont soumises aux méthodes appropriées de maîtrise et de contrôle interne.

Un système complet d'assurance qualité a été mis en œuvre pour les produits listés dans l'addendum n°2.

In addition, we declare under our own responsibility, according to the rules of article 12 of the European Directive 93/42/EEC, about the systems of several medical devices bearing the CE marking and listed in the attached addendum n°2 that :
- *we have verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions,*
- *and we have packaged the system and supplied relevant information to users incorporating relevant instructions from the manufacturers,*
- *and the whole activity is subjected to appropriate methods of internal control and inspection.*

Full Quality Assurance System has been submitted on the addendum n°2.

Ce document est valide pour tous les produits fabriqués jusqu'au 31 Decembre 2027.

This document is valid for all products manufactured until December 31st, 2027.

Fait à Paris, le 14 Juin 2024.

Paris, June 14th, 2024.

Rachid BOUJEDLI
[redacted]

Th[redacted]
Di
Chief Executive Officer

[redacted]

Déclaration CE de Conformité
EC Declaration of Conformity

Addendum n°1

Référence commerciale/ *Commercial reference*	Désignation	*Designation*	Qté par boite/ *Qty per box*	*GMDN*	Classe / *Class*	Directive 93/42/CEE	Certificat CE / *EC certificate*
A5.1350	CANULE DOUBLE COURANT DE SIMCOE ORIGINALE TROU D'ASPIRATION Ø 0,3 MM	ORIGINAL SIMCOE DUAL BORE CANNULA ASPIRATION PORT Ø 0,3 mm	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.1400	CANULE THX "CLUB DE GOLF" DOUBLE COURANT TROU D'ASPIRATION Ø 0,3 MM	THX "CLUB DE GOLF" I/A CANNULA ASPIRATION PORT Ø 0,3 mm	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.1450	TUBE SILICONE POUR CANULE THX 1 M	SILICONE TUBE FOR THX CANNULA 1 m	1	47240	I	Annexe VII (DDM 93/42/CEE)	/
A5.1460	CANULE DE CHALAZION	CHALAZION CANNULA	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.1465	CANULE DE CHALAZION POUR GAUCHER	CHALAZION CANNULA FOR LEFT HANDED SURGEON	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.1470	CANULE DE CHALAZION POUR LASIK	CHALAZION LASIK CANNULA	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.1600	CANULE POUR HYDRODISSECTION	HYDRO DISSECTION CANNULA	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.2000	CANULE POUR HEALON	HEALON CANNULA	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.2113	CANULE DE RYCROFT Ø 0,3 MM	RYCROFT CANNULA Ø 0,3 mm	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.2114	CANULE DE RYCROFT Ø 0,4 MM	RYCROFT CANNULA Ø 0,4 mm	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.2200	CANULE DE BARRAQUER BOUT OLIVAIRE DELICAT	BARRAQUER CANNULA DELICATE OLIVE TIP	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.4100	CANULE GRATTEUSE COURBE	CURVED ABRASIVE CANNULA	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.4200	CANULE GRATTEUSE DE CHARLEUX	CHARLEUX ABRASIVE CANNULA	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.4300	CANULE GRATTEUSE DE KRATZ	KRATZ ABRASIVE CANNULA	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A5.6010	CANULE DE GASTAUD II	GASTAUD II CANNULA	1	17899	I	Annexe VII (DDM 93/42/CEE)	/
A6.1300	PINCE DE KELMAN MAC PHERSON 11 MM	KELMAN MAC PHERSON FORCEPS 11 mm	1	62469	I	Annexe VII (DDM 93/42/CEE)	/
A6.1500	PINCE D'UTRATA CORPS PLAT DROIT MOUSSE	UTRATA FORCEPS VAULTED SHANKS STRAIGHT BLUNT TIPS	1	62469	I	Annexe VII (DDM 93/42/CEE)	/
A6.1510	PINCE D'UTRATA CORPS PLAT COURBE MOUSSE	UTRATA FORCEPS VAULTED SHANKS CURVED BLUNT TIPS	1	62469	I	Annexe VII (DDM 93/42/CEE)	/
[redacted]1520	PINCE DE CORYDON CORPS ROND COURBE POINTU 11 MM	CORYDON FORCEPS CYSTOTOME SHAPED TIPS SHANKS CURVED POINTED TIPS 11 mm	1	62469	I	Annexe VII (DDM 93/42/CEE)	/
[redacted]1530	PINCE DE CORYDON TITANE CORPS PLAT COURBE POINTU 11 MM	CORYDON TITANIUM FORCEPS VAULTED SHANKS CURVED POINTED TIPS 11 mm	1	62469	I	Annexe VII (DDM 93/42/CEE)	/
[redacted]1540	PINCE D'UTRATA TITANE CORPS PLAT COURBE MOUSSE 11 MM	UTRATA TITANIUM FORCEPS VAULTED SHANKS CURVED BLUNT TIPS 11 mm	1	62469	I	Annexe VII (DDM 93/42/CEE)	/

[redacted]

EC Declaration of Conformity

according to the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

***Class I** Medical Device (non-sterile)*

CE

Manufacturer:	**Jiangmen Haichuan Technology Development Co., Ltd.**
Address:	No.207-1 Chaolian Zhenxing Avenue, Pengjiang District, Jiangmen City, Guangdong Province,China
SRN:	CN-MF-000047653

We, the manufacturer, declare under our sole responsibility that the medical device(s) hereafter

Product Name:	**Non-sterile single use warming blanket**
Type/model:	**Refer to attached model list**
Intended Purpose:	The Warming Blanket is designed for use with a forced air warming unit to provide active perioperative warming for adult and paediatric patients requiring induced hyperthermia or localized temperature increase.
Classification:	Class I according to Annex VIII of the MDR
Basic UDI-DI:	697561677WBLANKETNS88

is/are in conformity with the relevant provisions and requirements of the Council and the parliament regulation (EU) 2017/745 for medical device and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.

Conformity assessment route:	EC Declaration of Conformity + Technical Documentation (Annex II) + Technical Documentation on Post-Market Surveillance (Annex III)

Applied harmonized standards and Common Specification	ISO 13485:2016	ISO 15223-1:2021	ISO 10993-10:2023
	ISO 14971:2019	ISO 10993-5:2009	ISO 20417-2021
	ISO 10993-1: 2020	IEC 60601-2-35:2020	ISO 10993-23:2021

Notified Body: **Address:** **Identification Number:** **EC Certificate(s):**	Not Applicable for Non-sterile Class I Device
ISO Certificate(s):	Registration No.J25QY0153R0S

European Representative (ER):	Share Info GmbH
SRN:	DE-AR-000005132
Address:	Am Schulzentrum 12, 41564 Kaarst, Germany Tel: 0179 5666 508

Authorized Signatory Person:	Chuan Wen 文川	**Title:**	General Manager

Signature (on behalf of the manufacturer)

Signed on:	June 03, 2025	Place:	Jiangmen, Guangdong, China

Attachment: Model List of Non-sterile Single Use Warming Blanket

Model No.	Description	Specification (cm)
002	Full Access Underbody-A	205 x 100
012	Large Pediatric Underbody-A	160 x 100
019	Chest Access Blanket	180 x 80
HC-302	Adult Torso Warming Blanket	208.5 x 100
HC-304	Surgical Access	200 x 110
HC-308	Lithotomy Underbody	170 x 100
HC-309	Adult Full Body	200 x 110
HC-310	Lower Body	128 x 100
HC-312	Dual Port Torso	120 x 100
HC-313	Full Access Underbody-C	195 x 80
HC-319	Multi-Position Upper Body	215 x 100
HC-320	Large Pediatric Underbody-B	160 x 84
HC-322	Paediatric Full Body	150 x 100
HC-330	Full Access Underbody-B	205 x 100
HC-331	Small Pediatric Underbody-A	129 x 100
HC-336	Cath Lab Blanket-B	165 x 77.5
HC-337	Multi-Access	200 x 110
HC-338	Paediatric Outpatient	150 x 80
HC-339	Adult Outpatient	200 x 100
HC-342	Cath Lab Blanket-A	195 x 77.5
HC-343	Small Pediatric Underbody-B	98 x 75

[redacted]

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Iscon Surgicals Limited

22/4 Heavy Industrial Area
Jodhpur, Rajasthan 342003
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:

OPHTHALMIC CANNULAE	Class IIa
OPHTHALMIC INSTRUMENTS	Class Is
OPHTHALMIC BLADES	Class IIa

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.	544100 MR2
Certificate unique ID	170772703
Effective date	2020-12-07
Expiry date	2024-05-26
Frankfurt am Main	2020-12-07

DQS Medizinprodukte GmbH

[redacted]

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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

[redacted]

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Iscon Surgicals Limited

22/4 Heavy Industrial Area,
Jodhpur, Rajasthan 342003
India

Date: 2024-08-05

Notified Body Confirmation Letter
Reference: 1000179759

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance 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

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Iscon Surgicals Limited

22/4 Heavy Industrial Area,
Jodhpur, Rajasthan 342003

India

SRN: IN – MF – 000009763

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices. The transition timelines that apply to the devices covered by this letter, 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

[redacted]

- 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)

On behalf of the Notified Body,

[redacted]

Amruta Bhave
Regulatory Affairs Manager

DQS Medizinprodukte GmbH
Managing Directors:
Sigrid Uhlemann
Heinrich von Mettenheim

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Germany

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info-med@dqs.de
www.dqsglobal.com

Registered in Frankfurt a.M.
AG HRB 83350
VAT: DE 260 263 917

[redacted]

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 and Basic UDI-DI (as proposed by the manufacturer within the 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
OPHTHALMIC CANNULAE	Class IIa	N/A	Cert # 544100 MR2 NB# 0297
OPHTHALMIC BLADES	Class IIa	N/A	Cert # 544100 MR2 NB# 0297
OPHTHALMIC INSTRUMENTS	Class IIa	N/A	Cert # 544100 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 and Basic UDI-DI (as proposed by the manufacturer within the 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
2024-08-05	1000179759 -1	Initial Creation
	Cert-ID	description of change (e.g. removal of device XYZ from Table 2)

DQS Medizinprodukte GmbH
Managing Directors:
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[redacted]