CERTIFICATE

This is to certify that the company

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

20-22 rue Louis Armand
75015 Paris
France

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Design, manufacturing, control and sale of sterile and non sterile implantable medical devices for ophthalmology.
Design, manufacturing, control and sale of sterile and non sterile medical devices for ophthalmology.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)

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

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	549168 MDSAP16
Certificate unique ID	170783451
Effective date	2023-05-26
Expiry date	2026-05-25
Frankfurt am Main	2023-05-26

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, info-med@dqs.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.
The validity of this certificate can only be verified by the QR-code.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 549168 MDSAP16
Certificate unique ID: 170783451
Effective date: 2023-05-26

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

20-22 rue Louis Armand
75015 Paris
France

Audited site	REPs FEI No.: site scope and country-specific requirements
549169 **FRANCE CHIRURGIE INSTRUMENTATION SAS (FCI S.A.S.)** 20-22 rue Louis Armand 75015 Paris France	Headquarter office and Sales, Human resources. -AUS (a), BRA, CND, JPN, USA (a,b,c,d) REPS FEI No.: F004212
549170 **FRANCE CHIRURGIE INSTRUMENTATION SAS (FCI S.A.S.)** 2 Rue Carl Zeiss 25000 Besancon France	Design and Manufacturing activities. -AUS (a), BRA, CND, JPN, USA (a,b,c,d) REPs FEI No.: F004202
549171 **FCI Sud Vel Industrial Complex** Royal Road, Mapou Leclezio, 30410 GOODLANDS, MAURITIUS Mauritius	Manufacturing activities. -AUS (a), BRA, CND, JPN, USA (a,b,c,d) REPs FEI No.: F004213

Annex to certificate
Certificate registration No.: 549168 MDSAP16
Certificate unique ID: 170783451
Effective date: 2023-05-26

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

20-22 rue Louis Armand
75015 Paris
France

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821