



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:

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.

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 (TECHNICAL COOPERATION PROGRAMME III WITH CHINESE-TAIPEI)

Certificate registration no. 549168 TCP III
Certificate unique ID 170783455
Effective date 2023-05-26
Expiry date 2026-05-25
Frankfurt am Main 2023-05-26

DQS Medizinprodukte GmbH

W luca

Sigrid Uhlemann Managing Director

Amruta Bhave Product Manager

Amsula Blave







Annex to certificate

Certificate registration No.: 549168 TCP III

Certificate unique ID: 170783455

Effective date: 2023-05-26

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

Resources.

20-22 rue Louis Armand 75015 Paris France

Location Scope

549169

FRANCE CHIRURGIE INSTRUMENTATION SAS Headquarter office and Sales, Human

20-22 rue Louis Armand 75015 Paris

549170

France

FRANCE CHIRURGIE INSTRUMENTATION SAS Design and Manufacturing activities. (FCI S.A.S.)

2 Rue Carl Zeiss 25000 Besancon France

549171

FCI Sud Vel Industrial Complex

Royal Road, Mapou Leclezio, 30410 GOODLANDS, MAURITIUS Mauritius

Manufacturing activities.