EU Quality Management Certificate

This is to certify that the company

SIS Ltd., Surgical Instrument Systems

Allmendstrasse 11
2562 Port
Switzerland

SRN: CH-MF-000025017

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III 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 Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	540874 MDR2017Q
Certificate ID	1000167722
Effective date	2024-03-01
Expiry date	2029-01-31
Frankfurt am Main,	2024-03-01

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Annex to EU Quality Management Certificate
SRN of Manufacturer: CH-MF-000025017
Certificate ID: 1000167722

Authorised Representative of the company:

Ziemer Ophthalmology (Deutschland) GmbH

Kronenstr. 38
79211 Denzlingen
Germany

SRN: DE-AR-000005638

Device categories and variants covered by this certificate:

Device category:	**MDA 0202: Active non-implantable imaging devices utilising non-ionizing radiation**
Product name:	410.030.004 Galilei G4
Risk classification:	IIa
Basic-UDI-DI:	764016775CMSGALGK
Intended purpose:	Imaging of the eye

Device category:	**MDA 0202: Active non-implantable imaging devices utilising non-ionizing radiation**
Product name:	410.030.007 Galilei G6
Risk classification:	IIa
Basic-UDI-DI:	764016775CMSGALGK
Intended purpose:	Imaging of the eye

Examinations and tests performed:
540874_A209785MED_01 dated 2023-12-22
540874_A211475MED_02 Galilei dated 2023-11-19

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	2024-02-01	1000116093	Change of the products names