DECLARATION OF CONFORMITY

Legal Manufacturer and Authorised Representative

Legal Manufacturer Name:	**SIS Ltd, Surgical Instrument Systems**
Legal Manufacturer Address:	Allmendstrasse 11, 2562 Port, Switzerland
SRN (Single Registration Number) *CHRN (Swiss Single Registration Number):*	CH-MF-000025017 CHRN-MF-20000150
Authorised Representative Name	Ziemer Ophthalmology (Deutschland) GmbH
Authorised Representative Address:	Kronenstraße 38, DE-79211 Denzlingen, Germany
SRN of Authorised Representative:	DE-AR-000005638

Medical Devices

Name of medical device	*Basic UDI-DI*	*Catalogue number*	*Classification*	*Intended use*
Galilei G4	764016775CMSGALGK	410.030.004	IIa	Images of the eye
Galilei G6	764016775CMSGALGK	410.030.007	IIa	Images of the eye

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

ziemer OPHTHALMOLOGY

Notified Body

Notified Body Name:	**DQS Medizinprodukte GmbH**
Notified Body Address:	August-Schanz-Strasse 21, 60433 Frankfurt am Main, Germany
Notified Body Number:	0297
Conformity assessment procedure:	EU MDR 2017/745 Annex IX (Certificate 540874 MDR2017Q)
Applied harmonized standards, national standards or general standards or Common Specifications:	EN ISO 13485; EN ISO 14971; EN ISO 15223-1; EN ISO 20417; EN 62366-1; EN ISO 10993-1; EN ISO 15004-1; EN 60601-1; EN 60601-1-2; EN 60601-1-6; EN 60601-1-9; EN 60825-1; EN 62304

We, **SIS Ltd, Surgical Instrument Systems** hereby declare under our sole responsibility that the products specified above are medical devices according to article 2(1) of the MDR Regulation 2017/745 and they meet the basic safety and performance requirements according to Annex I of the Regulation. This declaration is supported by the Quality Management System approval to ISO 13485 issued by **DQS Medizinprodukte GmbH**.

VALIDITY

This Declaration of Conformity remains valid until 31.01.2029.

Port, 06.02.2024

F. Ziemer
President & CEO

M. Peisino
PRRC, D QM & RA