DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

ziemer OPHTHALMOLOGY

Manufacturer:
SIE AG, Surgical Instrument Engineering
Allmendstrasse 11
2562 Port
Switzerland

We declare under our sole responsibility that the following medical devices of **class IIb** (« devices »)

• * FemtoLaser System (articulate arm:	0 mm)	Art. No. 510.002.001
• * FemtoLaser System (articulate arm:	-100 mm)	Art. No. 510.002.002
• * FemtoLaser System (articulate arm:	-60 mm)	Art. No. 510.002.003
• FEMTO LDV Z2		Art. No. 510.003.002
• FEMTO LDV Z4		Art. No. 510.003.004
• FEMTO LDV Z6		Art. No. 510.003.006
• FEMTO LDV Z8		Art. No. 510.003.008

and following medical devices of **class IIa** (« accessories »)

• Procedure Pack for Corneal Surgery	
○ Ø 8.5mm	Art. No. 510.700.012
○ Ø 9.0mm	Art. No. 510.700.013
○ Ø 9.5mm	Art. No. 510.700.014
○ Ø 10.0mm	Art. No. 510.700.015
○ Ø 10.5mm	Art. No. 510.700.016
○ Liquid	Art. No. 510.700.118
• Procedure Pack for Cataract Surgery	Art. No. 510.700.117
• Disposable Suction Tubing	Art. No. 510.701.270
• Disposable Casing Set	Art. No. 510.701.220
• Suction Ring Mounting Set	
○ 90 µm, Ø 8.5 mm	Art. No. 510.710.119
○ 90 µm, Ø 9.0 mm	Art. No. 510.710.129
○ 90 µm, Ø 9.5 mm	Art. No. 510.710.139
○ 90 µm, Ø 10.0 mm	Art. No. 510.710.149
○ 100 µm, Ø 8.5 mm	Art. No. 510.710.110
○ 100 µm, Ø 9.0 mm	Art. No. 510.710.120
○ 100 µm, Ø 9.5 mm	Art. No. 510.710.130
○ 100 µm, Ø 10.0 mm	Art. No. 510.710.140
○ 110 µm, Ø 8.5 mm	Art. No. 510.710.111
○ 110 µm, Ø 9.0 mm	Art. No. 510.710.121
○ 110 µm, Ø 9.5 mm	Art. No. 510.710.131
○ 110 µm, Ø 10.0 mm	Art. No. 510.710.141
○ 140 µm, Ø 8.5 mm	Art. No. 510.710.114
○ 140 µm, Ø 9.0 mm	Art. No. 510.710.124
○ 140 µm, Ø 9.5 mm	Art. No. 510.710.134
○ 140 µm, Ø 10.0 mm	Art. No. 510.710.144
○ 200 µm, Ø 8.5 mm	Art. No. 510.710.112
○ 200 µm, Ø 9.0 mm	Art. No. 510.710.122
○ 200 µm, Ø 9.5 mm	Art. No. 510.710.132
• Suction Ring Mounting Set for LASIK	
○ Ø 8.5mm	Art. No. 510.700.200
○ Ø 9.0mm	Art. No. 510.700.201
○ Ø 9.5mm	Art. No. 510.700.202
○ Ø 10.0mm	Art. No. 510.700.203
• Suction Ring Mounting Set for Corneal Surgery	
○ Ø 8.5mm	Art. No. 510.700.206
○ Ø 9.0mm	Art. No. 510.700.207
○ Ø 9.5mm	Art. No. 510.700.208
○ Ø 10.0mm	Art. No. 510.700.204
• Suction Ring Mounting Set for Advanced Corneal Surgery	
○ Ø 8.5mm	Art. No. 510.700.209
○ Ø 9.0mm	Art. No. 510.700.210
○ Ø 9.5mm	Art. No. 510.700.211
○ Ø 10.0mm	Art. No. 510.700.205
• LCS Suction Ring Mounting Set	
○ 8.5 mm	Art. No. 510.710.157
○ 9.0 mm	Art. No. 510.710.151
○ 9.5 mm	Art. No. 510.710.154
○ 10.0 mm	Art. No. 510.710.160
• LCS InterShields	
○ d450 µm	Art. No. 510.710.305
○ d420 µm	Art. No. 510.710.308
○ d390 µm	Art. No. 510.710.311
○ d360 µm	Art. No. 510.710.314
○ d330 µm	Art. No. 510.710.317
○ d300 µm	Art. No. 510.710.320
○ d200 µm	Art. No. 510.710.605
• Titanium Suction Ring	
○ Ø 6.5 mm	Art. No. 510.510.008
○ 7.0 mm	Art. No. 510.510.005
○ Ø 7.5 mm	Art. No. 510.510.006
○ Ø 8.0 mm	Art. No. 510.510.007
○ Ø 8.5 mm	Art. No. 510.510.001
○ Ø 9.0 mm	Art. No. 510.510.002
○ Ø 9.5 mm	Art. No. 510.510.003
○ Ø 10.0 mm	Art. No. 510.510.004

are in conformity with the provisions of the directive **93/42/EEC**, as amended, and with national implementing legislation;

Applied harmonized standards: EN ISO 13485; EN ISO 14971; EN ISO 15223-1; EN 1041; EN ISO 10993; EN ISO 11135-1; EN ISO 11137; EN ISO 11607; EN 60601-1; EN 60601-1-2; EN 60601-1-6; EN 60601-2-22; EN 62366; EN 556-1; * Note: the legacy devices (marked with * above) were developed according to older versions of EN 60601-1. Nevertheless, their conformity with the most recent versions is assessed by the subsequent test of the newest devices.

Conformity assessment procedure: **93/42/ EEC Annex II (excl. Section 4) – (Certificate 333427 MR2)**

Notified Body: DQS GmbH, August-Schanz-Strasse 21, 60433 Frankfurt am Main, Deutschland (NB-No. 0297)

We hereby also declare that the accessories are designed exclusively for the devices and they cannot work with any other system, and that the devices are useless without their accessories.

This declaration remains valid until 17.10.2021

Port, 10.04.2018

F. Ziemer, CEO

M. Peisino, D QM&RA