DECLARATION OF CONFORMITY

Legal Manufacturer and Authorised Representative

Legal Manufacturer Name:	**SIE AG, Surgical Instrument Engineering**
Legal Manufacturer Address:	Allmendstrasse 11, 2562 Port, Switzerland
SRN (Single Registration Number): *CHRN (Swiss Single Registration Number):*	CH-MF-000025018 CHRN-MF-20000149
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*
FEMTO LDV Z2	764016775FLMDEVGN	510.003.002	IIb	Creation of corneal incisions
FEMTO LDV Z4	764016775FLMDEVGN	510.003.004	IIb	Creation of corneal incisions
FEMTO LDV Z6	764016775FLMDEVGN	510.003.006	IIb	Creation of corneal incisions
FEMTO LDV Z8	764016775FLMDEVGN	510.003.008	IIb	Resection of cornea or of ocular surface
FEMTO Z8 NEO	764016775FLMDEVGN	510.003.009	IIb	Resection of cornea or of ocular surface

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES AND PROCEDURE PACKS STATEMENT

Medical Device Accessories

Medical Device Accessories available as Sale Unit:

Name of medical device accessory	*Basic UDI-DI*	*Catalogue number*	*Classification*	*Intended use*
Procedure Pack for Corneal Surgery 8.5mm	764016775PPACKSKP	510.700.012	IIa	Resection of cornea or of ocular surface
Procedure Pack for Corneal Surgery 9.0mm	764016775PPACKSKP	510.700.013	IIa	Resection of cornea or of ocular surface
Procedure Pack for Corneal Surgery 9.5mm	764016775PPACKSKP	510.700.014	IIa	Resection of cornea or of ocular surface
Procedure Pack for Corneal Surgery 10.0mm	764016775PPACKSKP	510.700.015	IIa	Resection of cornea or of ocular surface
Procedure Pack for Corneal Surgery 8.5mm SLIM	764016775PPACKSKP	510.700.020	IIa	Resection of cornea or of ocular surface
Procedure Pack for Corneal Surgery 9.0mm SLIM	764016775PPACKSKP	510.700.021	IIa	Resection of cornea or of ocular surface
Procedure Pack for Corneal Surgery 9.5mm SLIM	764016775PPACKSKP	510.700.022	IIa	Resection of cornea or of ocular surface
Procedure Pack for Corneal Surgery 10.0mm SLIM	764016775PPACKSKP	510.700.023	IIa	Resection of cornea or of ocular surface
LCS InterShields d450 µm	764016775PPACKSKP	510.710.305	IIa	Creation of corneal incisions
LCS InterShields d420 µm	764016775PPACKSKP	510.710.308	IIa	Creation of corneal incisions
LCS InterShields d390 µm	764016775PPACKSKP	510.710.311	IIa	Creation of corneal incisions
LCS InterShields d360 µm	764016775PPACKSKP	510.710.314	IIa	Creation of corneal incisions
LCS InterShields d330 µm	764016775PPACKSKP	510.710.317	IIa	Creation of corneal incisions
LCS InterShields d300 µm	764016775PPACKSKP	510.710.320	IIa	Creation of corneal incisions
LCS InterShields d200 µm	764016775PPACKSKP	510.710.605	IIa	Creation of corneal incisions

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES AND PROCEDURE PACKS STATEMENT

Medical Device Accessories used to assemble Procedure Packs as per Article 22 of MDR 2017/745:

Name of medical device accessory	*Basic UDI-DI*	*Catalogue number*	*Classification*	*Intended use*
Procedure Pack for Corneal Surgery Liquid	764016775PPACKSKP	510.700.118	IIa	Resection of cornea or of ocular surface
Procedure Pack for Corneal Surgery Liquid SLIM	764016775PPACKSKP	510.700.124	IIa	Resection of cornea or of ocular surface
Procedure Pack for Cataract Surgery	764016775PPACKSKP	510.700.117	IIa	Resection of cornea or of ocular surface
Procedure Pack for Cataract Surgery SLIM	764016775PPACKSKP	510.700.119	IIa	Resection of cornea or of ocular surface
Disposable Suction Tubing	764016775PPACKSKP	510.701.270	IIa	Creation of corneal incisions
Disposable Casing Set	764016775PPACKSKP	510.701.220	IIa	Creation of corneal incisions
Suction Ring Mounting Set 90 µm, 8.5 mm	764016775PPACKSKP	510.710.119	IIa	Creation of corneal incisions
Suction Ring Mounting Set 90 µm, 9.0 mm	764016775PPACKSKP	510.710.129	IIa	Creation of corneal incisions
Suction Ring Mounting Set 90 µm, 9.5 mm	764016775PPACKSKP	510.710.139	IIa	Creation of corneal incisions
Suction Ring Mounting Set 90 µm, 10.0 mm	764016775PPACKSKP	510.710.149	IIa	Creation of corneal incisions
Suction Ring Mounting Set 100 µm, 8.5 mm	764016775PPACKSKP	510.710.110	IIa	Creation of corneal incisions
Suction Ring Mounting Set 100 µm, 9.0 mm	764016775PPACKSKP	510.710.120	IIa	Creation of corneal incisions
Suction Ring Mounting Set 100 µm, 9.5 mm	764016775PPACKSKP	510.710.130	IIa	Creation of corneal incisions
Suction Ring Mounting Set 100 µm, 10.0 mm	764016775PPACKSKP	510.710.140	IIa	Creation of corneal incisions
Suction Ring Mounting Set 110 µm, 8.5 mm	764016775PPACKSKP	510.710.111	IIa	Creation of corneal incisions
Suction Ring Mounting Set 110 µm, 9.0 mm	764016775PPACKSKP	510.710.121	IIa	Creation of corneal incisions
Suction Ring Mounting Set 110 µm, 9.5 mm	764016775PPACKSKP	510.710.131	IIa	Creation of corneal incisions
Suction Ring Mounting Set 110 µm, 10.0 mm	764016775PPACKSKP	510.710.141	IIa	Creation of corneal incisions
Suction Ring Mounting Set 140 µm, 8.5 mm	764016775PPACKSKP	510.710.114	IIa	Creation of corneal incisions
Suction Ring Mounting Set 140 µm, 9.0 mm	764016775PPACKSKP	510.710.124	IIa	Creation of corneal incisions

Name of medical device accessory	*Basic UDI-DI*	*Catalogue number*	*Classification*	*Intended use*
Suction Ring Mounting Set 140 µm, 9.5 mm	764016775PPACKSKP	510.710.134	IIa	Creation of corneal incisions
Suction Ring Mounting Set 140 µm, 10.0 mm	764016775PPACKSKP	510.710.144	IIa	Creation of corneal incisions
Suction Ring Mounting Set for LASIK 8.5mm	764016775PPACKSKP	510.700.200	IIa	Creation of corneal incisions
Suction Ring Mounting Set for LASIK 9.0mm	764016775PPACKSKP	510.700.201	IIa	Creation of corneal incisions
Suction Ring Mounting Set for LASIK 9.5mm	764016775PPACKSKP	510.700.202	IIa	Creation of corneal incisions
Suction Ring Mounting Set for LASIK 10.0mm	764016775PPACKSKP	510.700.203	IIa	Creation of corneal incisions
Suction Ring Mounting Set for Corneal Surgery 8.5mm	764016775PPACKSKP	510.700.206	IIa	Creation of corneal incisions
Suction Ring Mounting Set for Corneal Surgery 9.0mm	764016775PPACKSKP	510.700.207	IIa	Creation of corneal incisions
Suction Ring Mounting Set for Corneal Surgery 9.5mm	764016775PPACKSKP	510.700.208	IIa	Creation of corneal incisions
Suction Ring Mounting Set for Corneal Surgery 10.0mm	764016775PPACKSKP	510.700.204	IIa	Creation of corneal incisions
Suction Ring Mounting Set for Advanced Corneal Surgery 8.5mm	764016775PPACKSKP	510.700.209	IIa	Creation of corneal incisions
Suction Ring Mounting Set for Advanced Corneal Surgery 9.0mm	764016775PPACKSKP	510.700.210	IIa	Creation of corneal incisions
Suction Ring Mounting Set for Advanced Corneal Surgery 9.5mm	764016775PPACKSKP	510.700.211	IIa	Creation of corneal incisions
Suction Ring Mounting Set for Advanced Corneal Surgery 10.0mm	764016775PPACKSKP	510.700.205	IIa	Creation of corneal incisions
LCS Suction Ring Mounting Set 8.5 mm	764016775PPACKSKP	510.710.157	IIa	Creation of corneal incisions
LCS Suction Ring Mounting Set 9.0 mm	764016775PPACKSKP	510.710.151	IIa	Creation of corneal incisions
LCS Suction Ring Mounting Set 9.5 mm	764016775PPACKSKP	510.710.154	IIa	Creation of corneal incisions

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES AND PROCEDURE PACKS STATEMENT

Name of medical device accessory	*Basic UDI-DI*	*Catalogue number*	*Classification*	*Intended use*
LCS Suction Ring Mounting Set 10.0 mm	764016775PPACKSKP	510.710.160	IIa	Creation of corneal incisions

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 : 333427 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 11135; EN ISO 11137-1; EN ISO 11137-2; EN ISO 11607-1; EN ISO 11607-2; EN 60601-1;EN 60601-1-2; EN 60601-1-6;EN 60601-1-9; EN 60601-2-22; EN 60825-1; EN 62304; EN 556-1

We, **SIE AG, Surgical Instrument Engineering** hereby declare under our sole responsibility that the products specified above are medical devices according to article 2(1) of the Medical Device Regulation (EU) 2017/745 and they meet the general 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**.

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.

PROCEDURE PACKS STATEMENT

In compliance with article 22 of the Medical Device Regulation (EU) 2017/745 (MDR 2017/745), we hereby also declare that the Procedure Packs described in Table 1 are a composition of different medical devices bearing the CE marking and procedure packs as per Article 22, put together within their intended purpose and within the limits of use specified by their manufacturers, in order to be placed on the market. The mutual compatibility of the devices is verified in accordance with the manufacturers' instructions. The components are combined according to internal monitoring, verification and validation processes and to the manufacturers' instructions. Relevant information is conveyed to users incorporating relevant instructions from the manufacturers.

To this aim, SIE AG acts as a Procedure Packs Producer under SRN CH-PR-000023323 and CHRN-MF-20000148.

This declaration is valid for all procedure packs, respectively their components as described in Table 1.

The article numbers marked with (*) or (**) in Table 1:

- Have NO CE mark on this packaging level according to Article 22 of MDR 2017/745
- Do not appear on the Declaration of Conformity and on the CE certificate.

The definitions of the asterisk variations in Table 1 are given below:

*Asterisk variation **

The following sales units are “procedure packs” according to article 22 of MDR 2017/745:

- “Procedure Pack Cataract Surgery” (Ref. 510.700.017)
- “Procedure Pack Cataract Surgery SLIM” (Ref. 510.700.019)
- “Procedure Pack Corneal Surgery Liquid” (Ref. 510.700.018), and
- “Procedure Pack Corneal Surgery Liquid SLIM” (Ref, 510.700.024)

Each of these procedure packs contain 10 (ten) of the following components:

- 10 Single units of either:
    - “Procedure Pack Cataract Surgery” (Ref. 510.700.117)
    - “Procedure Pack Cataract Surgery SLIM” (Ref. 510.700.119)
    - “Procedure Pack Corneal Surgery Liquid” (Ref. 510.700.118), or
    - “Procedure Pack Corneal Surgery Liquid SLIM” (Ref. 510.700.124)

  These single units are manufactured by SIE AG. They are class IIa medical device accessories (CE0297, listed in the Declaration of Conformity under “Medical device accessories used to assemble procedure packs as per article 22 of MDR 2017/745”).
- 10 Drape Sets (Ref. 105554).

The Drape Set is assembled by Jiangsu Xuhe Medical Technology Co., Ltd,., which identifies it with the following reference number: 1230611178A.

*Asterisk variation ***

The following sales units are “procedure packs” according to article 22 of MDR 2017/745:

- “Procedure Pack Ø X.X mm, XXX µm flap thickness” (Ref. 510. 701.0XX)
- “Procedure Pack LASIK Ø X.X mm” (Ref. 510. 700.00X)
- “Procedure Pack Corneal Surgery Ø X.X mm” (Ref. 510.700.00X)
- “Procedure Packs Advanced Corneal Surgery Ø X.X mm” (Ref. 510.700.0XX)
- “Procedure Packs LCS” (Ref. 510.710.0X0)

Each of these procedure packs (box of 10) contains 10 (ten) single “procedure packs* as per Article 22 of MDR 2017/745 (Ref. 510.70X.1XX), which are composed of:

- 1 x Disposable Casing Set (Ref. 510.701.220)

This Disposable Casing is manufactured by SIE AG and is a Class IIa medical device (CE0297, listed in the Declaration of Conformity as “Medical device accessories used to assemble procedure packs as per article 22 of MDR 2017/745”).

- 1 x Disposable Suction Tubing (Ref. 510.701.270)

  This Disposable Suction Tubing is manufactured by SIE AG and is a Class IIa medical device (CE0297, listed in the Declaration of Conformity as “Medical device accessories used to assemble procedure packs as per article 22 of MDR 2017/745”).

- 1 x Suction Ring Mounting Set (SRMS) (Ref. 510.710.1XX and 510.700.2XX)

  This SRMS is manufactured by SIE AG and is a Class IIa medical device (CE0297, listed in the Declaration of Conformity as “Medical device accessories used to assemble procedure packs as per article 22 of MDR 2017/745”).

  The Suction Ring Mounting Set is the component defining the cutting parameters of the Procedure Pack. All other components are identical in all Procedure Packs.

- 1 x OP-TOWEL (Ref. 103814)

  This OP-TOWEL is manufactured by Mölnlycke Health Care AG and it is a Class Is medical device (CE2797). Mölnlycke Health Care AG identifies the OP-TOWEL with the following reference number: 706401.

Except of the OP-Towel and the Drape Set, the components of the procedure packs do not have an UDI-DI as they are:

- Manufactured by SIE AG, and
- Not sold separately.

The article numbers without any asterisks in Table 1 are listed in the Declaration of Conformity as they are considered as:

- Medical device accessories available as Sale Unit, or
- Medical device accessories used to assemble procedure packs as per article 22 of MDR 2017/745.

TABLE 1 – Overview of the identification of the Procedure Packs as medical device accessories or procedure packs as per Article 22 of the MDR

Designation of the Procedure Pack	REF Nr. Box of 10 (sales unit)	REF Nr. Single Unit	Designation of corresponding characteristic component	REF Nr. Component
Classic - Procedure Packs				
Procedure Pack Ø 8.5mm,110µm flap thickness	510.701.011**	510.701.111**	Suction Ring Mounting Set 110 µm, Ø 8.5 mm	510.710.111
Procedure Pack Ø 9.0mm,110µm flap thickness	510.701.021**	510.701.121**	Suction Ring Mounting Set 110 µm, Ø 9.0 mm	510.710.121
Procedure Pack Ø 9.5mm,110µm flap thickness	510.701.031**	510.701.131**	Suction Ring Mounting Set 110 µm, Ø 9.5 mm	510.710.131
Procedure Pack Ø 10.0mm,110µm flap thickness	510.701.041**	510.701.141**	Suction Ring Mounting Set 110 µm, Ø 10.0 mm	510.710.141
Procedure Pack Ø 8.5mm,140µm flap thickness	510.701.014**	510.701.114**	Suction Ring Mounting Set 140 µm, Ø 8.5 mm	510.710.114
Procedure Pack Ø 9.0mm,140µm flap thickness	510.701.024**	510.701.124**	Suction Ring Mounting Set 140 µm, Ø 9.0 mm	510.710.124
Procedure Pack Ø 9.5mm,140µm flap thickness	510.701.034**	510.701.134**	Suction Ring Mounting Set 140 µm, Ø 9.5 mm	510.710.134
Procedure Pack Ø 10.0mm,140µm flap thickness	510.701.044**	510.701.144**	Suction Ring Mounting Set 140 µm, Ø 10.0 mm	510.710.144
Procedure Pack Ø 8.5mm,90µm flap thickness	510.701.009**	510.701.119**	Suction Ring Mounting Set 90 µm, Ø 8.5 mm	510.710.119
Procedure Pack Ø 9.0mm,90µm flap thickness	510.701.029**	510.701.129**	Suction Ring Mounting Set 90 µm, Ø 9.0 mm	510.710.129
Procedure Pack Ø 9.5mm,90µm flap thickness	510.701.039**	510.701.139**	Suction Ring Mounting Set 90 µm, Ø 9.5 mm	510.710.139
Procedure Pack Ø 10.0mm,90µm flap thickness	510.701.049**	510.701.149**	Suction Ring Mounting Set 90 µm, Ø 10.0 mm	510.710.149
Procedure Pack Ø 8.5mm,100µm flap thickness	510.701.010**	510.701.110**	Suction Ring Mounting Set 100 µm, Ø 8.5 mm	510.710.110
Procedure Pack Ø 9.0mm,100µm flap thickness	510.701.020**	510.701.120**	Suction Ring Mounting Set 100 µm, Ø 9.0 mm	510.710.120
Procedure Pack Ø 9.5mm,100µm flap thickness	510.701.030**	510.701.130**	Suction Ring Mounting Set 100 µm, Ø 9.5 mm	510.710.130
Procedure Pack Ø 10.0mm,100µm flap thickness	510.701.040**	510.701.140**	Suction Ring Mounting Set 100 µm, Ø 10.0 mm	510.710.140
Z - Procedure Packs				
Procedure Pack LASIK Ø 8.5mm	510.700.000 A**	510.700.100 A**	Suction Ring Mounting Set for LASIK Ø 8.5mm	510.700.200 A
Procedure Pack LASIK Ø 9.0mm	510.700.001**	510.700.101**	Suction Ring Mounting Set for LASIK Ø 9.0mm	510.700.201
Procedure Pack LASIK Ø 9.5mm	510.700.002**	510.700.102**	Suction Ring Mounting Set for LASIK Ø 9.5mm	510.700.202
Procedure Pack LASIK Ø 10.0mm	510.700.003**	510.700.103**	Suction Ring Mounting Set for LASIK Ø 10.0mm	510.700.203
Procedure Pack Corneal Surgery Ø 10.0mm	510.700.004**	510.700.104**	Suction Ring Mounting Set for Corneal Surgery Ø 10.0mm	510.700.204
Procedure Pack Corneal Surgery Ø 9.5mm	510.700.008**	510.700.108**	Suction Ring Mounting Set for Corneal Surgery Ø 9.5mm	510.700.208
Procedure Pack Corneal Surgery Ø 9.0mm	510.700.007**	510.700.107**	Suction Ring Mounting Set for Corneal Surgery Ø 9.0mm	510.700.207
Procedure Pack Corneal Surgery Ø 8.5mm	510.700.006**	510.700.106**	Suction Ring Mounting Set for Corneal Surgery Ø 8.5mm	510.700.206
Procedure Pack Advanced Corneal Surgery Ø 10.0mm	510.700.005**	510.700.105**	Suction Ring Mounting Set for Advanced Corneal Surgery Ø 10.0mm	510.700.205
Procedure Pack Advanced Corneal Surgery Ø 9.5mm	510.700.011**	510.700.111**	Suction Ring Mounting Set for Advanced Corneal Surgery Ø 9.5mm	510.700.211
Procedure Pack Advanced Corneal Surgery Ø 9.0mm	510.700.010**	510.700.110**	Suction Ring Mounting Set for Advanced Corneal Surgery Ø 9.0mm	510.700.210
Procedure Pack Advanced Corneal Surgery Ø 8.5mm	510.700.009**	510.700.109**	Suction Ring Mounting Set for Advanced Corneal Surgery Ø 8.5mm	510.700.209
LCS - Procedure Packs & Intershields				
Procedure Pack LCS Ø 8.5mm	510.710.040**	510.701.187**	LCS Suction Ring Mounting Set Ø 8.5 mm	510.710.157
Procedure Pack LCS Ø 9.0mm	510.710.020**	510.701.190**	LCS Suction Ring Mounting Set Ø 9.0 mm	510.710.151
Procedure Pack LCS Ø 9.5mm	510.710.030**	510.701.193**	LCS Suction Ring Mounting Set Ø 9.5 mm	510.710.154
Procedure Pack LCS Ø 10.0mm	510.710.050**	510.701.196**	LCS Suction Ring Mounting Set Ø 10.0 mm	510.710.160
Intershield d200 for LCS	510.710.605	510.710.505	Intershield d200, Dicke 50µm, verp, steril	510.710.705
Intershield d300 for LCS	510.710.320	510.710.220	Intershield d300, Dicke 200µm, verp, steril	510.710.420
Intershield d330 for LCS	510.710.317	510.710.217	Intershield d330, Dicke 170µm, verp, steril	510.710.417
Intershield d360 for LCS	510.710.314	510.710.214	Intershield d360, Dicke 140µm, verp, steril	510.710.414
Intershield d390 for LCS	510.710.311	510.710.211	Intershield d390, Dicke 110µm, verp, steril	510.710.411
Intershield d420 for LCS	510.710.308	510.710.208	Intershield d420, Dicke 80µm, verp, steril	510.710.408

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES AND PROCEDURE PACKS STATEMENT

Designation of the Procedure Pack	REF Nr. Box of 10 (sales unit)	REF Nr. Single Unit	Designation of corresponding characteristic component	REF Nr. Component
Intershield d450 for LCS	510.710.305	510.710.205	Intershield d450, Dicke 50µm, verp, steril	510.710.405
Procedure Pack for Cataract & Corneal Surgery Z8				
Procedure Pack for Cataract Surgery	510.700.017[*]	510.700.117	N/A	N/A
Procedure Pack for Corneal Surgery 8.5	510.700.012	510.700.112	N/A	N/A
Procedure Pack for Corneal Surgery 9.0	510.700.013	510.700.113	N/A	N/A
Procedure Pack for Corneal Surgery 9.5	510.700.014	510.700.114	N/A	N/A
Procedure Pack for Corneal Surgery 10.0	510.700.015	510.700.115	N/A	N/A
Procedure Pack for Corneal Surgery Liquid	510.700.018[*]	510.700.118	N/A	N/A
Procedure Pack for Cataract Surgery – SLIM	510.700.019[*]	510.700.119	N/A	N/A
Procedure Pack for Corneal Surgery 8.5 – SLIM	510.700.020	510.700.120	N/A	N/A
Procedure Pack for Corneal Surgery 9.0 – SLIM	510.700.021	510.700.121	N/A	N/A
Procedure Pack for Corneal Surgery 9.5 – SLIM	510.700.022	510.700.122	N/A	N/A
Procedure Pack for Corneal Surgery 10.0 – SLIM	510.700.023	510.700.123	N/A	N/A
Procedure Pack for Corneal Surgery Liquid – SLIM	510.700.024[*]	510.700.124	N/A	N/A

NOTES:

[A] Not for sale anymore

VALIDITY

This Declaration of Conformity and Procedure Packs Statement remain valid until 23.05.2028.

Port, 23.04.2024

F. Ziemer
President & CEO

M. Peisino
PRRC, D QM & RA