



CERTIFICATO CE

Certificato n. 1991/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

OPTIKON 2000 SPA

00138 ROMA (RM) - VIA DEL CASALE DI SETTEBAGNI 13 (ITA) - Italy

mantiene nello stabilimento di:

00138 ROMA (RM) - VIA DEL CASALE DI SETTEBAGNI 13 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Dispositivi per chirurgia oftalmica

Dispositivi per diagnostica oftalmica

Accessori per chirurgia oftalmica monouso

Accessori per chirurgia oftalmica riutilizzabili

Accessori per diagnostica oftalmica

Modd. come da documento allegato "Optikon 2000 S.p.A. CE products" rev. AS del 19/09/2018; valido solo se provvisto del timbro IMQ.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

DM17-0014306-01; DM18-0026831-01; DM18-0025372-01; DM18-0027164-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2018-05-02
Data aggiornamento: 2018-09-20
Sostituisce: 2018-05-02
Data scadenza: 2023-09-19

IMQ



EC CERTIFICATE

Certificate No 1991/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

OPTIKON 2000 SPA

00138 ROMA (RM) - VIA DEL CASALE DI SETTEBAGNI 13 (ITA) - Italy

manages in the factory of:

00138 ROMA (RM) - VIA DEL CASALE DI SETTEBAGNI 13 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Ophthalmic surgical equipments

Ophthalmic diagnostic equipments

Single use ophthalmic surgical accessories

Reusable ophthalmic surgical accessories

Ophthalmic diagnostic accessories

Type ref. as to annexed document "Optikon 2000 S.p.A. CE products" rev. AS dated 19/09/2018; valid only if provided with IMQ stamp.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM17-0014306-01; DM18-0026831-01; DM18-0025372-01; DM18-0027164-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 2018-05-02
Updated: 2018-09-20
Substitution Date: 2018-05-02
Expiry Date: 2023-09-19

IMQ

CE products

rev. AS dated 19/09/2018

The following devices have been added to the EC Certificate N. 1991/MDD:

- Reusable ophthalmic surgical accessories:

117006

- Ophthalmic surgical equipments:

111009, 111010, 111014, 121013, 121014, 1S11009

The Trade Mark of the following devices is PhysIOL s.a.

111009, 111010, 111014, 121013, 121014

The Trade Mark of the following device is SIFI

1S11009



2018-09-20

REF	description	class
<i>OPHTHALMIC DIAGNOSTICAL ACCESSORIES</i>		
A-SCAN PROBES		
143001	10 MHZ BIOMETRY PROBE	II a
143011	8 MHZ DIAGNOSTIC A-SCAN PROBE	II a
B-SCAN PROBES		
143002	12 MHz B-SCAN PROBE	II a
143003	20 MHz B-SCAN PROBE	II a
143004	35 MHz B-SCAN PROBE	II a
143005	50 MHz B-SCAN PROBE	II a
143012	25MHZ PROBE FOR IMMERSION B-SCAN	II a
143200	12 MHZ B-SCAN PROBE	II a
143300	20 MHZ B-SCAN PROBE	II a
143500	50 MHz B-SCAN PROBE	II a
143600	35 MHZ B-SCAN PROBE	II a
149014	35MHZ TRANSDUCER FOR B-SCAN PROBE	II a
149015	50MHZ TRANSDUCER FOR B-SCAN PROBE	II a
149016	25MHZ TRANSDUCER FOR B-SCAN PROBE	II a
PACHIMETRY PROBES		
153003	20 MHz STRAIGHT PACHYMETRY PROBE	II a
153004	20 MHz ANGLED PACHYMETRY PROBE	II a
153005	50 MHz STRAIGHT PACHYMETRY PROBE	II a



2018-09-20

REF	description	class
<i>OPHTHALMIC DIAGNOSTICAL EQUIPMENT</i>		
CORNEAL TOPOGRAPHY AND ABERROMETRY		
161104	KERATRON	II a
161204	KERATRON SCOUT	II a
161301	KERATRON PICCOLO	II a
161401	KERATRON ONDA	II a
161501	KERATRON	II a
161601	KERATRON NOVA	II a
162215	SCOUT IR PUPILLOMETRY UPGRADE KIT	II a
162216	CONTACT LENS ANALYZER KIT	II a
ULTRASOUND DIAGNOSTICAL EQUIPMENT		
141002	BIOLINE	II a
141010	HISCAN TOUCH BASIC	II a
141011	HISCAN TOUCH FULL	II a
141012	JANUS BIOMETER/PACHYMETER	II a
151003	PACLINE	II a



2018-09-20

REF	description	class
OPHTHALMIC SURGICAL ACCESSORIES - REUSABLE		
CHANNELLING DEVICES		
114101	I/A HANDPIECE, LONG BARREL	II a
117001	I/A TUBING SET WITH ACS3 FOR PULSAR	II a
117002	ACS3 DEVICE FOR PULSAR	II a
117003	I/A TUBING SET FOR QUASAR/P4000	II a
117004	I/A TUBING SET FOR PULSAR2	II a
117006	REUSABLE EASYSYS I/A CASSETTE	II a
124013	IRRIGATION TUBE FOR 23G KIT (3 PCS.)	II a
125101	AIR INJECTION TUBE	II a
129006	CHARLES HANDPIECE	II a
129007	TUBE FOR ENDODIATHERMY PROBE (2 PCS)	II a
129008	ASPIRATION HANDPIECE	II a
129010	TUBE FOR CHARLES HANDPIECE (2 PCS)	II a
129019	LUER ADAPTER	II a
172323	CHARLES ASPIRATION HANDPIECE	II a
CRYOSURGERY PROBES		
133001	CRYO PROBE FOR CATARACT	II b
133002	CRYO PROBE FOR RETINA, BALL	II b
133003	CRYO PROBE FOR RETINA, SPATULA	II b
133004	CRYO PROBE FOR RETINA, "T" SHAPED	II b
133005	CRYO PROBE FOR RETINA, "BONNET"	II b
133006	CRYO PROBE FOR GLAUCOMA	II b
133007	CRYO PROBE ENDOVITREAL	II b
DIATHERMY ACCESSORIES		
115103	DIATHERMY HANDLE FOR SUBRETINAL DRAINAGE	II b
115210	DIATHERMY ELECTRODE, DARK GREY	II b
115301	DIATHERMY FORCEPS	II b
115302	DIATHERMY PENCIL ERASER	II b
115303	20G ENDODIATHERMY PROBE	II b
115305	19G ENDODIATHERMY PROBE WITH REFLUX	II b
171502	ENDODIATHERMY PROBE, 20 GA	II b
I/A ACCESSORIES		
114201	STRAIGHT I/A CANNULA,SIL. SLEEVE,0.3 19G	II a
114203	ANGLED I/A CANNULA SIL. SLEEVE,0.3MM 19G	II a
114205	STRAIGHT I/A CANNULA,METAL SLEEVE, 0.3MM	II a
114207	ANGLED I/A CANNULA, METAL SLEEVE, 0.3MM	II a
114209	CURVED I/A CANNULA, METAL SLEEVE, 0.3MM	II a
114211	12 O'CLOCK I/A CANNULA,METAL SLEEVE, 0.3	II a
114212	90° I/A CANNULA, METAL SLEEVE, 0.3MM	II a



REF	description	class
114216	20G STRAIGHT I/A CANNULA,SIL.SLEEVE,0.3	II a
114217	20G ANGLED I/A CANNULA,SIL.SLEEVE,0.3	II a
114218	21G STRAIGHT I/A CANNULA,SIL.SLEEVE,0.3	II a
114219	21G ANGLED I/A CANNULA,SIL.SLEEVE,0.3	II a
114222	22G STRAIGHT I/A CANNULA,SIL.SLEEVE,0.3	II a
114223	22G ANGLED I/A CANNULA,SIL.SLEEVE,0.3	II a
114301	IRRIGATION PROBE FOR BIMANUAL TECHNIQUE	II a
114302	ASPIRATION PROBE FOR BIMANUAL TECHNIQUE	II a
124001	20G SCLERAL INFUSION CANNULA, ANGLED,3MM	II a
124002	20G SCLERAL INFUSION CANNULA, ANGLED,4MM	II a
124003	20G SCLERAL INFUSION CANNULA, ANGLED,6MM	II a
124004	SCLERAL INFUSION CANNULA, 4	II a
124005	20G SCLERAL INFUSION CANNULA, 6MM	II a
124012	23G SCLERAL INFUSION CANNULA, 4MM	II a
129011	23G ASPIRATION CANNULA	II a
129014	23G TROCAR KIT	II a
172316	0.6MM SCLERAL INFUSION CANNULA	II a
PHACOEMULSIFICATION HANDPIECES		
113101	PHACO HANDPIECE "SLIM 4"	II b
113103	PHACO HANDPIECE FOR QUASAR/P4000	II b
113107	PHACO HANDPIECE "SIX"	II b
113108	PHACO HANDPIECE WITH IOP SENSING	II b
171301	PHACO HANDPIECE "SLIM 4" (AMO THREAD)	II b
PHACOEMULSIFICATION TIPS		
113201	19G PHACO TIP, 5°	II a
113202	19G PHACO TIP, 15°	II a
113203	19G PHACO TIP, 30°	II a
113204	19G PHACO TIP, 45°	II a
113205	20G PHACO TIP, 15°	II a
113206	20G PHACO TIP, 30°	II a
113207	20G PHACO TIP, 45°	II a
113208	22G PHACO TIP, 5°	II a
113209	22G PHACO TIP, 30°	II a
113210	22G PHACO TIP, 45°	II a
113211	22G PROGRESSIVE PHACO TIP	II a
113215	19G PROGRESSIVE PHACO TIP	II a
113216	2.5MM INCISION PHACO TIP, 30	II a
113217	PARS PLANA PHACO TIP	II a
113218	19G PEZZOLA DIAPHRAGM PHACO TIP	II a
113219	20G PHACO TIP FOR BIMANUAL, 5°	II a
113220	20G PHACO TIP FOR BIMANUAL, 15°	II a
113221	20G PHACO TIP FOR BIMANUAL, 30°	II a



REF	description	class
113222	20G PHACO TIP FOR BIMANUAL, ANGLED	II a
113223	PARS PLANA PHACO TIP (4-40 UNC THREAD)	II a
113224	20G PHACO TIP, BENT	II a
113228	19G BICONICAL PHACO TIP	II a
113229	20G BORDIN 'HI-FOLLOWABILITY' PHACO TIP	II a
113230	20G BICONICAL PHACO TIP	II a
113232	19G BORDIN 'HI-FOLLOWABILITY' PHACO TIP	II a
113233	BICONICAL PHACO TIP, 21G	II a
113234	20G PHACO TIP, 5°	II a
113235	21G PHACO TIP, 5°	II a
113236	21G PHACO TIP, 15°	II a
113237	21G PHACO TIP, 30°	II a
113238	BICONICAL PHACO TIP, 22G	II a
113239	21G BORDIN 'HI-FOLLOWABILITY' PHACO TIP	II a
113240	20G FLARED PHACO TIP	II a
113241	21G FLARED PHACO TIP	II a
113242	22G FLARED PHACO TIP	II a
172112	DIAPHRAGM TIP 19G 30°	II a
172113	DIAPHRAGM TIP 20G 30°	II a
172114	PROGRESSIVE PHACO TIP	II a
SLEEVES		
113301	SILICONE SLEEVE FOR 19G TIPS (3 PCS)	II a
113306	PTFE SLEEVE FOR 19G PROGRESSIVE TIPS	II a
113307	SILICONE SLEEVE FOR 21G TIPS (3 PCS)	II a
113308	SILICONE SLEEVE FOR 20G TIPS (3 PCS)	II a
113309	SILICONE SLEEVE FOR 22G TIPS (3 PCS)	II a
114401	SLEEVE FOR I/A CANNULA&ANT.VITR. (3 PCS)	II a



2018-09-20

REF	description	class
OPHTHALMIC SURGICAL ACCESSORIES - SINGLE-USE		
SINGLE USE ACTUATING KITS		
192518	ADAPTER SYRINGE TUBING LLF-ASSISTANT	I s
192519	ADAPTER SYRINGE TUB. LLF-REVOLUTION	I s
192520	ACTUATING KIT FOR SILICONE OIL SYRINGE	I s
SINGLE USE AIR INJECTION TUBES		
179203	DISP. AIR INJECTION TUBE	II a
192512	AIR INJECTION TUBE	II a
192513	AIR INJECTION TUBE WITH FILTER	II a
SINGLE USE ANTERIOR VITRECTOMY PROBES		
192304	ANTERIOR VITRECTOMY PROBE	II b
SINGLE USE ASPIRATION CANNULAS		
192120	20G SOFT TIP CANNULA	II a
192123	23G SOFT TIP CANNULA	II a
192125	25G SOFT TIP CANNULA	II a
192130	20G BLUNT TIP CANNULA	II a
192133	23G BLUNT TIP CANNULA	II a
192135	25G BLUNT TIP CANNULA	II a
SINGLE USE ASPIRATION HANDPIECES		
192110	DISPOSABLE BACKFLUSH HANDLE, A/P	II a
192111	DISPOSABLE BACKFLUSH HANDLE, ACTIVE	II a
SINGLE USE CASSETTES		
191704	CASSETTE-COLLECT.BAG FOR PULSAR2	II a
SINGLE USE CONNECTORS		
192516	Y-CONNECTOR FOR AIR-INFUSION TUBE	II a
SINGLE USE DIATHERMY PROBES		
192620	20G ENDODIAT. BIPOLAR PROBE	II b
192623	23G ENDODIAT. BIPOLAR PROBE	II b
192625	25G ENDODIAT. BIPOLAR PROBE	II b
SINGLE USE DRAPES AND COVERS		
190807	R-REVOLUTION KIT EXT.+SCREEN/C+TRAY/C	I s
191602	SCREEN DRAPE + TRAY COVER KIT	I s
191603	SCREEN DRAPE	I s
191604	TRAY COVER	I s
191605	TRAY COVER	I s
191606	REMOTE CONTROL COVER	I s
191612	TRAY COVER	I s
196201	STERILE COVER FOR SCOUT STD CONE	I s
196203	STERILE COVER FOR SCOUT FAR CONE	I s



REF	description	class
SINGLE USE FIBER OPTIC ILLUMINATION PROBES		
179801	W/ANGLE DISP.F.OPT.FOR 3 WAY ADAPT.	II a
179802	STD.DISP.F.OPTIC FOR 3 WAYS ADAPTER	II a
192801	20G ENDOILLUMINATION PROBE	II a
192802	20G WIDE ANGLE ENDOILLUMINATION PROBE	II a
192803	20G ENDOILLUMINATION PROBE, MULTIPOINT	II a
192806	20G W/A ENDOILLUMINATION PROBE MULTIPOINT	II a
192807	23G ENDOILLUMINATION PROBE, MULTIPOINT	II a
192808	25G ENDOILLUMINATION PROBE, MULTIPOINT	II a
192809	23G W/A ENDOILLUMINATION PROBE, M/PORT	II a
192815	20G SHIELDED W/A ENDOILL. PROBE M/PORT	II a
192816	23G SHIELDED W/A ENDOILL. PROBE M/PORT	II a
SINGLE USE FLUID REMOVAL KITS		
179207	VISCOUS FLUID EXTRACTION KIT	II a
192525	19G VISCOUS FLUID REMOVAL KIT	II a
SINGLE USE I/A TUBING SETS AND CASSETTES		
179701	I/A TWIN PUMP CASSETTE W/TUBING	II a
191701	I/A TUBING S. W/O ACS3 FOR PULSAR	II a
191702	I/A TUBING SET W/ ACS3 FOR PULSAR	II a
191703	CASSETTE-I/A TUBING SET FOR PULSAR2	II a
192701	I/A TUBING SET FOR ANTARES 2000	II a
192702	CASSETTE-I/A TUBING SET ASSISTANT	II a
192703	ASSISTANT/P2 ESP HI-VAC EASYSYS KIT	II a
192704	R-EVOLUTION HI-VAC EASYSYS KIT	II a
SINGLE USE ILLUMINATION CHANDELIERS		
192804	18G CHANDELIER WITH ILLUM./IRRIG. M/PORT	II a
192805	20G CHANDELIER FOR ILLUM. M/PORT	II a
192817	25G CHANDELIER WITH ADJUST. POS., M/PORT	II a
SINGLE USE INFUSION KITS		
179206	DISP.SCL.INF.CANN.SIL.+STOPCOCK	II a
192521	20G SIL.INF.CANNULA/TUBE/STOPCOCK	II a
192523	20G BSS/SIL SCLERAL INF.CANNULA 3MM	II a
SINGLE USE IRRIGATION ADMINISTRATION SETS		
190700	INFUSION SET FOR CONTROLLED IRRIGATION	II a
190702	IRR.ADMINISTRATION SET W/DRIP CHAMBER	II a
SINGLE USE PHACO TIPS		
179111	PARS PLANA TIP, DISPOSABLE	II a
191200	20G 5° PHACO TIP	II a
191201	20G 15° PHACO TIP	II a
191203	20G 30° PHACO TIP	II a
191204	20G 45° PHACO TIP	II a



REF	description	class
SINGLE USE POSTERIOR VITRECTOMY PROBES		
179201	DISP. POST. VITRECTOMY PROBE	II b
192301	20G VITRECTOMY PROBE	II b
192302	25G VITRECTOMY PROBE	II b
192303	23G VITRECTOMY PROBE	II b
192313	23G OPTI-VIT TWEDGE VITREOUS CUTTER	II b
192315	25G OPTI-VIT TWEDGE VITREOUS CUTTER	II b
192317	27G OPTI-VIT TWEDGE VITREOUS CUTTER	II b
192318	23G PENDULAR TWEDGE VITREOUS CUTTER	II b
192320	20G MICROSCISSORS, 45°	II b
192323	23G MICROSCISSORS, 45°	II b
SINGLE USE SENSORS		
191005	PHACOEMULSIFICATION IOP SENSOR	I s
SINGLE USE STOPCOCKS		
192514	2-WAY STOPCOCK	II a
SINGLE USE SURGE SUPPRESSORS		
191004	KAWANO IRRIGATION SURGE SUPPRESSOR	II a
SINGLE USE SURGICAL KNIVES		
18912000	20G MVR KNIFE, STRAIGHT	II a
18912001	20G MVR KNIFE, ANGLED	II a
18912300	23G MVR KNIFE, STRAIGHT	II a
18912301	23G MVR KNIFE, ANGLED	II a
18912500	25G MVR KNIFE, STRAIGHT	II a
18921500	15° STAB KNIFE	II a
18921530	3.0MM DEPTH, 15° STAB KNIFE	II a
18921550	5.0MM DEPTH, 15° STAB KNIFE	II a
18921821	DB 1,8MM SLIT KNIFE, ANGLED	II a
18922200	22.5° STAB KNIFE	II a
18922301	2.3MM SLIT KNIFE, ANGLED	II a
18922321	DB 2,3MM SLIT KNIFE, ANGLED	II a
18922801	2.75MM SLIT KNIFE, ANGLED	II a
18922811	2.75MM DOUBLE BEVEL SLIT KNIFE, ANGLED	II a
18923000	30° STAB KNIFE	II a
18923001	3.0MM SLIT KNIFE, ANGLED	II a
18923011	3.0MM DOUBLE BEVEL SLIT KNIFE, ANGLED	II a
18923201	3.2MM SLIT KNIFE, ANGLED	II a
18923211	3.2MM DOUBLE BEVEL SLIT KNIFE, ANGLED	II a
18924500	45° STAB KNIFE	II a
18932500	250MICRON PRECISION DEPTH	II a
18942001	CRESCENT KNIFE BEVEL UP, ANGLED	II a
18952225	2.2 - 2.5MM TRAPEZ. SLIT KNIFE	II a



REF	description	class
18952629	2.6 - 2.9MM TRAPEZ. SLIT KNIFE	II a
18952932	2.85 - 3.2MM TRAPEZ. SLIT KNIFE	II a
18964001	4.1MM IMPLANT KNIFE, ANGLED	II a
18965201	5.2MM IMPLANT KNIFE, ANGLED	II a
18980601	0.6MM SIDE PORT KNIFE, ANGLED	II a
18980801	0.8MM SIDE PORT KNIFE, ANGLED	II a
SINGLE USE TROCAR KITS		
192201	25G TROCAR KIT	II a
192202	23G TROCAR SYSTEM, ONE-STEP	II a
192203	23G TROCAR SYSTEM, ONE-STEP WITH VALVE	II a
192223	23G TROCAR SYSTEM, ONE-STEP WITH VALVE	II a
192225	25G TROCAR SYSTEM, ONE-STEP WITH VALVE	II a



2018-09-20

REF	description	class
<i>OPHTHALMIC SURGICAL EQUIPMENT</i>		
111001	PULSAR "MINIMAL STRESS"	II b
111004	PULSAR2	II b
111005	PULSAR VER. 2	II b
111007	PULSAR2 ESP	II b
111009	R-EVO SMART E	II b
111010	R-EVO SMART S	II b
111012	R-EVOLUTION	II b
111014	R-EVOLUTION - PH	II b
121008	ASSISTANT "MINIMAL STRESS"	II b
121010	VIT MODULE FOR PULSAR2	II b
121012	R-EVOLUTION CR	II b
121013	R-EVO SMART CR	II b
121014	R-EVOLUTION CR - PH	II b
122007	REMOTE CONTROL FOR R-EVOLUTION	II b
128910	ENDOLASER UPGRADE MODULE	II b
131002	CRYO-LINE W/TUBE,FILTER,CARTRIDGE,FOOTSW	II b
1S11009	SIFI - PHACO	II b



2018-09-20