INFORMAȚII GENERALE DESPRE OFERTANT

1.	**Numele juridic al ofertantului:**	**Tehnomedica SRL**
2.	**Adresa juridică a ofertantului:**	Republica Moldova, mun.Chișinău, str. Ciuflea 38/1
3.	**Director:**	Tatiana Roibu
4.	**Telefon / Fax:**	022 601 102, 022 601 087
5.	**E-mail:**	tehnomedica_md@yahoo.com tehnomedicamd@gmail.com
6.	**Cont de decontare IBAN:**	MD65MO2224ASV98310887100
7.	**Banca:**	BC „Mobiasbanca – OTP Group” S.A., fil nr. 26 Negruzzi
8.	**Adresa poştală a băncii:**	Chișinău, str.Negruzzi 1
9.	**Codul băncii:**	MOBBMD22
10.	**Cod fiscal:**	1002600053256
11.	**Cod TVA:**	0207719

Director Tehnomedica SRL Tatiana Roibu

Semnătura:

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **1968** din **01.02.2019**

Denumirea completă: **SOCIETATEA CU RĂSPUNDERE LIMITATĂ «TEHNOMEDICA» .**
Denumirea prescurtată: **«TEHNOMEDICA» S.R.L. .**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1002600053256.**
Data înregistrării de stat: **17.04.2002.**
Sediul: **MD-2001, str. Ciuflea, 38/1, mun.Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1 Fabricarea utilajului medical şi chirurgical şi a dispozitivelor ortopedice;
2 Comerţul cu ridicata al produselor farmaceutice;
3 Comerţul cu amănuntul al produselor farmaceutice;
4 Practica medicală;
5 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
6 Activităţi de consultare pentru afaceri şi management.
Capitalul social: **5400** lei.
Administrator: ROIBU TATIANA,
Asociaţi:
1. ROIBU TATIANA 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 01.02.2019.

Specialist coordonator
tel. 022-20-7838

Clichici Elena

INSTITUŢIA PUBLICĂ AGENŢIA SERVICII PUBLICE IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0257484

Republica Moldova

AUTORIZAȚIE

Nr. 015333

REPUBLICA MOLDOVA
Primăria municipiului Chișinău

AUTORIZAȚIE

pentru amplasarea și funcționarea depozitelor

Nr. **24167** din **30.07.2010**

24167

Eliberată: **TEHNOMEDICA**
Societate cu răspundere limitată

Adresa: MUN.CHISINAU, SEC.CENTRU , Ciuflea str. , nr. 38/1
Cod fiscal: 1002600053256

MUN.CHISINAU, SEC.CENTRU , Ciuflea str. , nr. 38/1

depozit;
suprafața comercială: 31,2 m2
cu program de lucru: 09:00 - 17:00
zile de odihnă: Sîmbătă, Duminică

Grupurile de mărfuri:
Articole de tehnică și optică medicală.

Condiții speciale:
Respectarea strictă a: legilor privind protecția consumatorului; legislația lingvistică. Respectarea regulilor de depozitare și păstrare a mărfurilor. Respectarea regulilor sanitare și de bază ale comerțului. Respectarea sortimentului prevăzut în autorizație.

Autorizația este eliberată în baza deciziei Consiliului municipal Chișinău din 27.12.2007 nr, 13/4

_____ (semnătura solicitantului)

REPUBLICA MOLDOVA CONSILIUL MUNICIPAL CHIȘINĂU

Autorizația este valabilă: de la **30.07.2015** până la **30.07.2020**

Viceprimar _____ Grozavu Nistor

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chişinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com>

Către IMSP Spitalul Clinic Republican
”Timofei Moșneaga”

În atenția Grupului de lucru
al LP nr. ocds-b3wdp1-MD-1591879832356,
ID: 21024383 din 26.06.2020

Declarație privind respectarea condițiilor de livrare

Prin prezenta, declarăm că pentru produsele oferite în cadrul Licitației Publice nr. ocds-b3wdp1-MD-1591879832356, ID: 21024383 din 26.06.2020 privind **achiziționarea produselor oftalmologice etapa II pentru anul 2020,** livrarea va avea loc cu respectarea lanțului condițiilor de păstrare şi transportare.

Cu respect,

Director Tatiana Roibu

26.06.2020

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chişinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com>

Către IMSP Spitalul Clinic Republican
"Timofei Moșneaga"

În atenția Grupului de lucru
al LP nr. ocds-b3wdp1-MD-1591879832356,
ID: 21024383 din 26.06.2020

Declarație privind termenul de valabilitate a produselor

Prin prezenta, declarăm că, la livrarea produselor oferite în cadrul Licitației Publice nr. ocds-b3wdp1-MD-1591879832356, ID:21024383 din 26.06.2020 privind **achiziționarea produselor oftalmologice etapa II pentru anul 2020,** termenul de valabilitate va constitui 80% din termenul total al produsului, dar nu mai mic de 24 luni.

Cu respect,

Director Tatiana Roibu

26.06.2020

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chişinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com>

Către IMSP Spitalul Clinic Republican
"Timofei Moșneaga"

În atenția Grupului de lucru
al LP nr. ocds-b3wdp1-MD-1591879832356,
ID: 21024383 din 26.06.2020

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul Licitației Publice nr. ocds-b3wdp1-MD-1591879832356, ID:21024383 din 26.06.2020 privind **achiziționarea produselor oftalmologice etapa II pentru anul 2020.**

Cu respect,

Director Tatiana Roibu

26.06.2020

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 575415**

Issued To: **Geuder AG**
Hertzstraße 4
69126 Heidelberg
Germany

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-06-29** Date: **2019-05-28** Expiry Date: **2024-05-25**

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By Royal Charter

Certificate No: CE 575415

Certificate Scope:

Design, development and manufacture of devices for ophthalmology: Ultrasonic Handpieces; Single-Use Light Conductors / Fiber Optics, sterile; Fiber Optic Instruments, reusable; Single-Use Accessory Kits with Ultrasonic Tips, sterile; Ultrasonic tips, reusable; Single-Use Vitrectomy Instruments, sterile; Single-Use DMEK Cartridge, sterile; Single-Use-DMEK-Transportation Cartridge; Sclera Pins; Single-Use Iris Retractor, sterile; Vitrectomy Infusion Tube and Cutting Heads; Single-Use Trocar System, sterile; Single-Use Ophthalmic Cannula; Injection-/Infusion Tubing; Single-Use Tubing Sets, sterile; Tubing Sets, reusable; Cassettes; Single use vitreous cutters, sterile; Single-Use Vitrectors, sterile; Single-use LED Lightsource, sterile.
Those aspects of Annex II related to sterility in the design, development and manufacture of devices for ophthalmology: Single-Use Adapters, sterile; I/A Instruments, sterile.

Auslegung, Entwicklung und Herstellung von Produkten für die Ophthalmologie: Ultraschallhandgriffe; Einmal-Lichtleiter, steril; Kaltlichtinstrumente, wiederverwendbar; Einmal-Kits mit Ultraschallspitzen, steril; Ultraschallspitzen, wiederverwendbar; Einmal-Vitrektomiespitzen, steril; Einmal-DMEK-Kartusche, steril; Einmal-DMEK-Transportkartusche, steril; Skleranägel; Einmal-Irisretraktor, steril; Vitrektomie Infusionsrohr und Schneideköpfe; Einmal-Trokarsystem, steril; ophthalmologische Einmal-Kanülen; Injektions- / Infusionshalterungen; Einmal-Schlauchsysteme, steril; Schlauchsysteme, wiederverwendbar; Kassetten; Einmal-Vitrektoren, steril; Einmal-LED Lichtquellen, steril.
Die Aspekte des Anhangs II im Zusammenhang mit der Sterilität bei der Auslegung, Entwicklung und Herstellung von Einmal-Adaptern für Glasspritzen, steril; Spül- und Sauginstrumenten, steril.

First Issued: **2016-06-29** Date: **2019-05-28** Expiry Date: **2024-05-25**

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 575415

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
Class IIb		
MD 1105	Ultrasonic Handpieces	Used with ultrasound tips to perform phacoemulsification, a surgical procedure that uses ultrasonic energy to fragment (or emulsify) a cataractous lens and removes the lens material through a small incision.
Class IIa		
MD 0105	Single-use Light Conductors / Fiber Optics, sterile	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.
MD 0105	Single-use Light Conductors / Fiber Optics, sterile, incl. Uno Colorline	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.

First Issued: **2016-06-29** Date: **2019-05-28** Expiry Date: **2024-05-25**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 575415

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
MD 0105	Fiber Optic Instruments, reusable	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.
MD 0105	Single-use Accessory Kits with Ultrasonic Tips, sterile	Accessories and tips to be used with US-handpieces to perform phacoemulsification.
MD0105	Ultrasonic tips, reusable	US tips to be used with US-handpieces to perform phacoemulsification.
MD 0105	Single-use Vitrectomy Instruments Uno Colorline, sterile	For manipulation and crushing of intraocular tissue during pars plana vitrectomy. For usage in the posterior eye segment for cutting and gripping of ocular structures.
MD 0102	Single-use DMEK Cartridge, sterile	Used for Descemet Membrane Endothelial Keratoplasty, a special technique for corneal transplantation. For uploading and injecting descemet membrane transplant.
MD 0102	Single-use DMEK Transportation Cartridge, RAPID	Used for Descemet Membrane Endothelial Keratoplasty, a special technique for corneal transplantation. For uploading, transporting and injecting descemet membrane transplant.

First Issued: **2016-06-29** Date: **2019-05-28** Expiry Date: **2024-05-25**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 575415

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
MD 0105	Sclera Pins	To be used to occlude temporarily the exterior points of access (incisions) during surgeries in the posterior segment to minimize leakages of liquid or gases.
MD 0105	Single-use Iris Retractor, sterile	To be used dilate the iris mechanically.
MD 0105	Mega-Vit Vitrectomy Infusion Tube and Cutting Heads	Accessories to use with high speed drive for cutting and intraocular removal of the vitreous body.
MD 0105	Single-use Trocar System Uno Colorline, sterile	To open and keep the scleral incision (in the area of pars plana) in open state, so to allow access of different ophthalmic surgical instruments to the inside of the eye.

First Issued: **2016-06-29** Date: **2019-05-28** Expiry Date: **2024-05-25**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 575415

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
MD 0102	Single-use Ophthalmic Cannula	Used to supply or remove liquids such as saline solution (BSS), viscous liquids, PFCL, air or gases. Capsule polishing needles or vacuum cleaner needles with silicone tip can also be used to remove tissue or materials.
MD 0102	Injection/Infusion Tubing	Infusion Tubing: applying liquids and air. Injection tubing: applying viscous solutions into eyes in vitreoretinal surgery.
MD 0102	Single-use Tubing Sets, sterile	Irrigation and aspiration of aqueous solutions, air injections and silicone oil into the eye.
MD 0102	Tubing Sets, reusable	For irrigation and aspiration of aqueous solutions, air injections and silicone oil into the eye.
MD 0102	Cassettes	Connected to the ophthalmic system for irrigation and aspiration.
MD 1105	Single-use vitreous cutters, sterile	For removal of vitreous body from the eye.

First Issued: **2016-06-29** Date: **2019-05-28** Expiry Date: **2024-05-25**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 575415

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
MD 1105	Single-use Vitrectors, sterile, Uno Colorline	For removal of vitreous body from the eye.
MD 1105	OcuLED Single-use LED Lightsource, sterile	For endoillumination during ocular surgery.
Class Is		
MD 0105	Single-use Adapters, sterile	Used during the pneumatic injection of silicone oil into the eyes of patients. It is a protective holder for the glass syringes which are filled with silicone oil or viscous fluids. It is to prevent injuries in case the glass syringe breaks under the pressure.
MD 0102	I/A Instruments, sterile	Used in ophthalmological surgery, to remove liquids and tissue from the eye and irrigate the eye with air or balanced saline solution (BSS).

First Issued: **2016-06-29** Date: **2019-05-28** Expiry Date: **2024-05-25**

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Holds Certificate No: **FM 575411**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, development, manufacture, warehousing, distribution, installation and maintenance of ophthalmo-surgical instruments, active device systems and associated accessories, implants, sterilisation trays and containers.
Warehousing and distribution of gases, silicone oils, dyes, perfluorocarbons and semifluorinated alkanes for ophthalmology.

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2001-06-01
Latest Revision Date: 2020-05-18

Effective Date: 2020-05-26
Expiry Date: 2023-05-25

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Holds Certificate Number: **MD 575412**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-06-27
Latest Revision Date: 2020-05-18

Effective Date: 2020-05-26
Expiry Date: 2023-05-25

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Certificate No: **MD 575412**

Registered Scope:

Design, development, manufacture, warehousing, distribution, installation and maintenance of active and non active, sterile and non sterile ophthalmic surgical devices/systems, instruments and accessories, ophthalmic implants, sterilization trays and containers.
Warehousing and distribution of silicone oils, dyes, perfluorocarbons and semifluorinated alkanes for use as liquid intraocular endotamponades and gas-based intraocular tamponades and vitreous substitutes for the area of ophthalmology.
Auslegung, Entwicklung, Produktion, Lagerhaltung, Vertrieb, Installation und Instandhaltung von aktiven und nicht aktiven, sterilen und nicht sterilen ophthalmo-chirurgischen Geräten/Systemen, Instrumenten und Zubehör, ophthalmologischen Implantaten, Sterilisationsbehältern und Sterilisationscontainern.
Lagerhaltung und Vertrieb von Silikonölen, Färbemitteln, Perfluorcarbonverbindungen und semiflourierten Alkanen für die Verwendung als flüssige intraokulare Endotamponaden, gasförmige intraokulare Tamponaden und Glaskörperersatzstoffe im Einsatzbereich der Ophthalmologie.

Original Registration Date: 2016-06-27
Effective Date: 2020-05-26
Latest Revision Date: 2020-05-18
Expiry Date: 2023-05-25

bsi.

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3rd May 2018

Subject: Letter of Authenticity of EC Certificates

To Whom It May Concern

BSI is designated as a Notified Body under the European Medical Directive 93/42/EEC. BSI has conducted a conformity assessment against the EU Medical Device Directive 93/42/EEC Annex II and Annex V of the following medical device manufacturer:

GEUDER AG
Hertzstraße 4
69126 Heidelberg
Germany

BSI issued both EC Certificates ref. CE 575415 / CE 575413 to GEUDER AG with the following scopes:

CE 575415: Design, development and manufacture of active and non active, sterile and non sterile ophthalmic surgical devices/systems, instruments, accessories and ophthalmic implants.

CE 575413: Manufacture of non active, sterile and non sterile ophthalmic surgical products and accessories.
Those aspects of Annex V related to metrology in the manufacture of ophthalmic surgical measuring devices.
Those aspects of Annex V related to sterility in the manufacture of ophthalmic surgical irrigation/aspiration (I/A) instruments, single-use irrigation cannulas, single-use endoprobes, single-use fiber optics, single-use adapters for glass syringes and Bonn Injection Sets.

Under the EU Medical Device Directive a medical device manufacturer may prepare and complete a declaration of conformity for devices that fully meet the requirements of the Medical Device Directive and are within the scope of the Annex II and V Certificates. The medical device manufacturer listed above has provided a copy of a declaration of conformity for the devices listed herein.
BSI accepts that the devices identified in the tables are within the scope of BSI above certificates and therefore by following the declaration of conformity process and the requirements of the EU Member States, the medical device manufacturer is free to place these devices on the EU Market.

EC Certificate CE 575415:	Class	Device Reference
Megatron surgical systems (incl. G-28510 foot switch resp. G-28541)	IIb	G-28251E, G-28252E, G-28252EC, G-29850
Megatron S4 and Megatron S4 HPS surgical systems (incl. G-30543 foot switch)	IIb	G-60000, G-60002, G-60004, G-60010, G-60010-1, G-60012, G-60012-1,G-60013, G-60013-1,G-60014, G-60014-1,G-60015, G-60015-1,G-60017, G-60017-1,G-60020,G-60022, G-60022-1, G-28650
Endotron 532 nm surgical system (incl. G-61101 foot switch)	IIb	G-61100

Motor Handpiece for Micro-Keratron incl. motor cartridge	IIa	G-21032, G-21041
Mega-Vit Vitrectomy Cutting Systems	IIa	G-30900, G-30910, G-30920
Mega-Vit Infusion Tubes and Cutting Heads	IIa	G-30981, G-30982, G-30983, G-30985, G-30986, G-30987, G-30988, G-30995, G-30996
Single-Use Vitreous Cutters, sterile, and single-use Vitrectors, Uno Colorline, sterile	IIa	G-42001, G-42009, G-42301, G-42302, G-42501, G-42502, G-46001, G-46009, G-46301, G-46302, G-46501, G-46502, G-28167, G-28168, G-28172, G-28174, G-28177, G-28183
OcuLED Single-use LED Ligthsource , sterile	IIa	G-26401, G-26402, G-26403, G-26404, G-26405, G-26406, G-26431, G-26432,G 26433, G-26434, G-26435, G-26436
Ultrasonic tips, reusable	IIa	G-24040, G-24041, G-24050, G-24051, G-24055, G-24060, G-24061, G-24065, G-24070, G-24072, G-24310, G-24313
Single-Use Accessory Kits with Ultrasonic Tips, sterile	IIa	G-24080, G-24300 , G-24301, G-24302, G-24304
Ultrasonic Handpieces	IIb	G-24025, G-24027,G-28430, G-28431, G-30450, G-30440
Diathermy Instruments	IIb	G-25030, G-25032, G-25034, G-31215, G-31216, G-31218, G-31219
Single-Use Adapters, sterile	IIa	G-28766, G-28767, G-28768
Single-Use Retinal Tack	IIb	G-33437T
Single-Use DMEK Cartridge, sterile	IIa	G-38635, G-38630, G-38611
Single-Use Injection/Infusion Tubing, sterile	IIa	G-33462, G-33463, G-33482, G-34480, G-34481, G-34492
Single-Use Iris Retractor, sterile	IIa	G-34523
Single-Use Cannulas, sterile	IIa	G-34200, G-34205, G-34210, G-34215, G-34220, G-34225, G-34230, G-34235, G-34240, G-34245, G-34246, G-34255, G-34270, G-34271, G-34272, G-34275, G-34280, G-34290, G-34291, G-34292, G-34293, G-34294, G-34295, G-34296, G-34297, G-34298, G-34299
Single-Use Light Conductors / Fiber Optics, sterile, incl. Uno Colorline	IIa	G-26068, G-26069, G-26070, G-26071, G-26075, G-26076, G-26078, G-26079, G-42021, G-42022, G-42023, G-42321, G-42322, G-42323, G-42521, G-42522, G-42523, G-46021, G-46022, G-46023, G-46321, G-46322, G-46323, G-46521, G-46522, G-46523
Single-Use Silicone Implants for Retinal Detachment	IIb	G-34600, G-34602, G-34604, G-34606, G-34608, G-34610, G-34612, G-34614, G-34616, G-34618, G-34620, G-34622, G-34624, G-34626, G-34628, G-34630, G-34632, G-34634, G-34636, G-34638, G-34640, G-34642, G-34644, G-34645, G-34646, G-34647, G-34648, G-34650, G-34652, G-34654, G-

		34656, G-34658, G-34660, G-34662, G-34664, G-34666, G-34668, G-34670, G-34672, G-34674, G-34676, G-34678, G-34680, G-34682, G-34684, G-34686, G-34688, G-34690
Single-Use Vitrectomy Instruments Uno Colorline, sterile	IIa	G-42041, G-42042, G-42043, G-42044, G-42061, G-42341, G-42342, G-42343, G-42344, G-42361, G-42362, G-42541, G-42542, G-42544, G-42561, G-46041, G-46042, G-46341, G-46342, G-46343, G-46541, G-46542
Single-Use Trocar Systems Uno Colorline, sterile	IIa	G-42011, G-42019, G-42311, G-42319, G-42511, G-42512, G-46011, G-46311, G-46511
Eye Spheres	IIb	G-20216, G-20217, G-20218, G-20219, G-20220, G-20316, G-20317, G-20318, G-20319, G-20320, G-20416, G-20417, G-20418, G-20419, G-20420
Injection-/Infusion Tubing	IIa	G-32177, G-32180, G-32181, G-32182, G-33416, G-33420, G-33422, G-33425, G-33430, G-33433, G-33450, G-33451, G-33452, G-33470, G-33471, G-33472, G-33473, G-33474, G-33475, G-33484, G-33485, G-33486, G-33487, G-33490, G-33491, G-33492, G-33494, G-33495, G-33496, G-33497, G-37614, G-37616
Fiber Optic Instruments	IIa	G-26020, G-26030, G-26045, G-26095, G-26115, G-32113, G-32114
Cassettes	IIa	G-30150, G-30151, G-30161, G-30162, G-60700, G-60701, G-60750
Single-Use Tubing Sets, sterile	IIa	G-28091, G-28097, G-28098, G-28136, G-30114, G-30116, G-30118, G-30146, G-46000, G-28148, G-32696
Tubing Sets, reusable	IIa	G-22635,G-22700, G-24205, G-28130, G-28131, G-28132, G-28133, G-28134, G-28137, G-28140, G-28142, G-28144, G-28147, G-30139, G-30170, G-32697
Sclera Pins	IIa	G-33432, G-33435, G-33436, G-33441

EC Certificate CE 575413:	**Class**	**Device Reference**
Bonn Injection Set, sterile	Is	G-34710
Single-use Endoprobes Uno Colorline, sterile	IIa	G-61201, G-61202, G-61204, G-61205, G-61231, G-61232, G-61234, G-61235, G-61251, G-61252, G-61254, G-61255
Single-Use Light Conductors / Fiber Optics wide-angle, sterile	IIa	G-26074
Single-Use Irrigation Cannula, sterile	Is	G-34335
I/A Instruments, sterile	Is	G-34806
I/A Instruments, sterile, Single-use Backflush Handpiece	IIa	G-34289
Single-use cannula	IIa	G-34285
Single-Use Injection/Infusion Tubing, sterile	IIa	G-33468, G-33469, G-33488, G-33489
Single-Use Tubing Sets , sterile	IIa	G-30112
Single-Use Knives, sterile	IIa	G-34026, G-34031, G-34036, G-34041, G-34050, G-34051, G-34052, G-34053, G-34054, G-34055, G-34056, G-34057, G-34060, G-34061, G-34062, G-34063, G-34081, G-34086, G-

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		34091, G-34092, G-34093, G-34094, G-34096, G-34098, G-34106, G-34111, G-34120, G-34122, G-34124, G-34126, G-34131, G-34141, G-34146, G-34152, G-34176, G-34181, G-34191, G-34192, G-34196, G-34197
Single-use trephines	IIa	G-500001, G-510650, G-510725, G-510750, G-510775, G-510800, G-510850, G-510875, G-520400, G-520500, G-520550, G-520600, G-520625, G-520650, G-520675, G-520700, G-520725, G-520750, G-520775, G-520800, G-520825, G-520850, G-520875, G-520900, G-520950, G-521000, G-521050, G-521100, G-521150, G-521200, G-521250, G-521300, G-521350, G-521400, G-521450, G-521500, G-521550, G-521600, G-521650, G-521700, G-521800, G-530700, G-530725, G-530750, G-530775, G-530800, G-530825, G-530850, G-530875, G-530900, G-540600, G-540625, G-540650, G-540675, G-540700, G-540725, G-540750, G-540775, G-540800, G-540825, G-540850, G-540875, G-540900, G-540925, G-540950, G-560600, G-560625, G-560650, G-560675, G-560700, G-560725, G-560750, G-560775, G-560785, G-560800, G-560825, G-560850, G-560875, G-560900, G-560925, G-560950, G-570600, G-570650, G-570700, G-570725, G-750750, G-570775, G-570800, G-570825, G-570850, G-570875, G-570900
Measuring Instruments	Im	G-18645, G-18650, G-19349

Please contact the undersigned if there are any questions regarding this letter or the BSI certificates.

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