CERTIFICATO CE - SISTEMA COMPLETO DI GARANZIA DI QUALITÀ

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

APPROVAZIONE DEL SISTEMA DI QUALITÀ ATTUATO DA
APPROVAL OF THE QUALITY SYSTEM OPERATED BY

AL.CHI.MI.A S.R.L.

VIALE AUSTRIA 14 - 35020 PONTE SAN NICOLO' (PD) - ITALY

SITI / SITES

VIALE AUSTRIA 14 - 35020 PONTE SAN NICOLO' (PD) - ITALY

PER I SEGUENTI DISPOSITIVI O GRUPPI DI DISPOSITIVI / *FOR THE FOLLOWING DEVICES OR GROUPS OF DEVICES*

Endotamponi liquidi e gassosi per la chirurgia vitreoretinica e relativi accessori. Perfluorocarburi per la chirurgia vitreoretinica. Coloranti tissutali reversibili per evidenziare tessuti da asportare nel corso di procedure chirurgiche oftalmiche. Prodotti ed accessori per attività di Banca degli Occhi: dispositivi per il lavaggio, la conservazione ed il trasporto di tessuti destinati alla chirurgia oculare. Dispositivi medici e accessori sterili per oftalmologia. Prodotti per attività di Banca dei Tessuti: dispositivi per il lavaggio, la conservazione ed il trasporto di tessuti umani e cellule destinati al trapianto.

Liquid and gaseous intraocular tamponade for vitreoretinal surgery and related accessories. Perfluorocarbons for vitreoretinal surgery. Temporary tissue staining to visualize tissues to be extirpated during ophthalmic surgery. Products and accessories for Eye Banking: devices for rinsing, storage and transport of tissues intended for ocular surgery. Sterile medical devices and accessories for ophthalmology. Products for Tissue Banking: devices for rinsing, storage and transport of human tissues and cells intended for transplantation.

Certiquality S.r.l., Organismo Notificato n° 0546, certifica che il sistema di qualità
Certiquality S.r.l., Notified Body n°0546, certifies that the quality system

è conforme ai requisiti della Direttiva 93/42/CEE, Allegato **II** ad esclusione del punto 4
is in compliance with the requirements of Directive 93/42/EEC, Annex *excluding section 4*

RAPPORTO DI AUDIT N° / *AUDIT REPORT NO.* **11971/2/I**

CERTIFICATO N. / *CERTIFICATE N.* **11971/2/I**

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CONCESSIONE E IL MANTENIMENTO DELL'APPROVAZIONE DI SISTEMA QUALITA' AI SENSI DELLA DIRETTIVA 93/42/CEE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE REGULATIONS FOR AWARDING AND MAINTENANCE OF QUALITY SYSTEM APPROVAL IN ACCORDANCE WITH DIRECTIVE 93/42/EEC

Il SISTEMA QUALITÀ E' SOGGETTO A SORVEGLIANZA PERIODICA

THE QUALITY SYSTEM IS SUBJECT TO PERIODICAL SURVEILLANCE

LA VERIFICA DEL SISTEMA QUALITÀ E' LIMITATA AGLI ASPETTI DELLA FABBRICAZIONE CONCERNENTI LA CONFORMITÀ AI REQUISITI METROLOGICI PER I DISPOSITIVI DI CLASSE I CON FUNZIONE DI MISURA E AGLI ASPETTI DELLA FABBRICAZIONE CHE RIGUARDANO IL RAGGIUNGIMENTO E IL MANTENIMENTO DELLO STATO STERILE PER I DISPOSITIVI DI CLASSE I STERILE.

THE AUDIT OF THE QUALITY SYSTEM IS RESTRICTED TO THE ASPECTS OF MANUFACTURE CONCERNED WITH THE CONFORMITY OF THE DEVICES WITH METROLOGICAL REQUIREMENTS FOR DEVICES IN CLASS I WITH MEASURING FUNCTION AND WITH SECURING AND MAINTAINING STERILE CONDITIONS FOR DEVICE IN CLASSE I IN STERILE CONDITION

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO

THIS CERTIFICATE IS NOT VALID WITHOUT THE RELEVANT ANNEX

PRIMA EMISSIONE / *FIRST ISSUE* 28/02/2007

EMISSIONE CORRENTE / *CURRENT ISSUE* 21/05/2020

DATA DI SCADENZA / *EXPIRY DATE* 15/02/2022

IL PRESIDENTE - CESARE PUCCIONI

Mod. 5.20 ED 06 260517

ORGANISMO NOTIFICATO N° 0546

NOTIFIED BODY N° 0546

ALLEGATO AL CERTIFICATO N. **11971/2/I**

ANNEX TO CERTIFICATE N.

AL.CHI.MI.A S.R.L.

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VIALE AUSTRIA 14 - 35020 PONTE SAN NICOLO' (PD) - ITALY

ELENCO PRODOTTI / *PRODUCT LIST*

FT004: Endotamponi liquidi per la chirurgia vitreoretinica e relativi accessori / *Liquid intraocular tamponade for vitreoretinal surgery and related accessories*: RS-OIL 1000: (ref. RSO 002-00), (ref. RSO 003-00); RS-OIL 5000: (ref. RSO 004-00), (ref. RSO 005-00); RS-OIL 1300 (ref. RSO 008-00); RS-OIL 2000 (ref. RSO 012-00); RS-OIL 5700 (ref. RSO 009-00); RS-OIL ECS 1000: (ref. RSO 006-00); RS-OIL ECS 5000: (ref. RSO 007-00); RS-OIL ECS 1300 (ref. RSO 010-00); RS-OIL ECS 5700 (ref. RSO 011-00); RS-OIL ECS 2000 (ref. RSO 013-00); Fluid Injection/Removal Pack: (ref. FIR 001-00), (ref. FIR 002-00), (ref. FIR 003-00), (ref. FIR 004-00), (ref. FIR 005-00).

FT 004: Endotamponi gassosi per la chirurgia vitreoretinica e relativi accessori / *Gaseous intraocular tamponade for vitreoretinal surgery and related accessories*: GOT SF_6 20 (ref. GOT 002-00); GOT C_2F_6 16 (ref. GOT 004-00); GOT C_3F_8 12 (ref. GOT 006-00); GOT SF_6 multi (ref. GOT 007-00); GOT C_2F_6 multi (ref. GOT 008-00); GOT C_3F_8 multi (ref. GOT 009-00); GIS (ref. GIS 001-00); GIS small volume (ref. GIS 002-00); GOT Filtration and injection (ref. GIS 003-00).

FT 002: Coloranti tissutali reversibili utilizzati per evidenziare tessuti da asportare nel corso di procedure chirurgiche oftalmiche / *Temporary tissue staining to visualize tissues to be extirpated during ophthalmic surgery*: RS-Blue: (ref. RSB 001-00), (ref. RSB 002-00); Blue 018 HD (ref. RMB 002-00), view ILM (ref. RMB 003-00), TWIN (ref. RMB 004-00), VEDO (ref. VVA 001).

IL PRESENTE ALLEGATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO CERTIFICATO
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CERTIQUALITY S.r.l. ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
Via G. Giardino, 4 - 20123 Milano - Tel. 02/8069171 Fax. 02/86465295 certiquality@certiquality.it - www.certiquality.it

ORGANISMO NOTIFICATO N° 0546

NOTIFIED BODY N° 0546

ALLEGATO AL CERTIFICATO N. **11971/2/I**

ANNEX TO CERTIFICATE N.

AL.CHI.MI.A S.R.L.

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VIALE AUSTRIA 14 - 35020 PONTE SAN NICOLO' (PD) - ITALY

ELENCO PRODOTTI / *PRODUCT LIST*

FT 005: Perfluorocarburi per chirurgia vitreoretinica / *Perfluorocarbons for vitreoretinal surgery*: HPF8: (ref. HPF 001-00), (ref. HPF 002-00), (ref. HPF 019-00), (ref. HPF 020-00); HPF10: (ref. HPF 003-00), (ref. HPF 004-00), (ref. HPF 021-00), (ref. HPF 022-00).

FT 001: Prodotti ed accessori per attività di Banca degli Occhi: dispositivi per il lavaggio, la conservazione ed il trasporto di tessuti destinati alla chirurgia oculare / *Products and accessories for Eye Banking: devices for rinsing, storage and transport of tissues intended for ocular surgery*: CORNEAL CHAMBER (ref. CTC 001-01); PSS-L (ref. GRS 003-00); THIN-C (ref. CDM 001), Corneal *Float* (ref. CFD 001); Kerasave (ref. KER 002-00).

FT 008: Soluzioni sterili idratanti e lubrificanti per uso oftalmico / *Sterile hydrating and lubricating solutions for ophthalmic use*: eyeDRO (ref. EDO 001), (ref. EDO 002); OCIGEL (ref. OCI 001), (ref. OCI 002).

FT 016: Tubo di connessione sterile / *Sterile connection tubing*: ECT easy connection tubing (ref. ECT 001-01), (ref. ECT 002-00), (ref. ECT 003-00), (ref. ECT 004-00), (ref. ECT 005-01).

FT 010: Filtro sterile in PTFE per la filtrazione di perfluorocarburi / *Sterile PTFE filter for perfluorocarbon filtration*: Perfluorocarbon Filter (ref. PCF 001-00).

FT 013/ FT 014: Prodotti per attività di Banca dei Tessuti: dispositivi per il lavaggio, la conservazione ed il trasporto di tessuti umani e cellule destinati al trapianto / *Products for Tissue Banking: devices for rinsing, storage and transport of human tissues and cells intended for transplantation*: BASE (ref. BAS 007-00); BASE●128 (ref. BAS 005-00), (ref. BAS 006-00); CRYO●ON (ref. CRN 001-00), (ref. CRN 002-00), (ref. CRN 003-00); GLYO●ON (ref. GLY 001), (ref. GLY 002).

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EC Certificate Full Quality Assurance System: Certificate GB19/964588

The management system of

Network Medical Products Ltd

Coronet House, Kearsley Road, Ripon, North Yorkshire, HG4 2SG, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile single use Corneal trephines
Sterile single use DCR bodkins
Sterile single use canaliculus intubation sets
Sterile single use Ventilation tubes and grommets
Sterile single use CORONET corneal tissue delivery system
Sterile single use Donor trephine punch
Sterile and non sterile single use aspirating suction tubes and fine ends for the removal of particulates during ENT surgery

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 30 May 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 17 September 1997
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC 230480

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

EC Certificate Production Quality Assurance System: Certificate US19/819943513

The management system of

MedOne Surgical, Inc.

670 Tallevast Road, Sarasota, FL, 34243, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Sterile ophthalmic devices: cannulae, brushes, picks and related accessories (tubing, backflush devices and injection kits), knives and forceps for ophthalmic surgery.

For placing on the market of Class IIb covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 16 December 2019 until 11 April 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 14 February 2003
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MC/ 208342

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com