Technology meets Anatomy

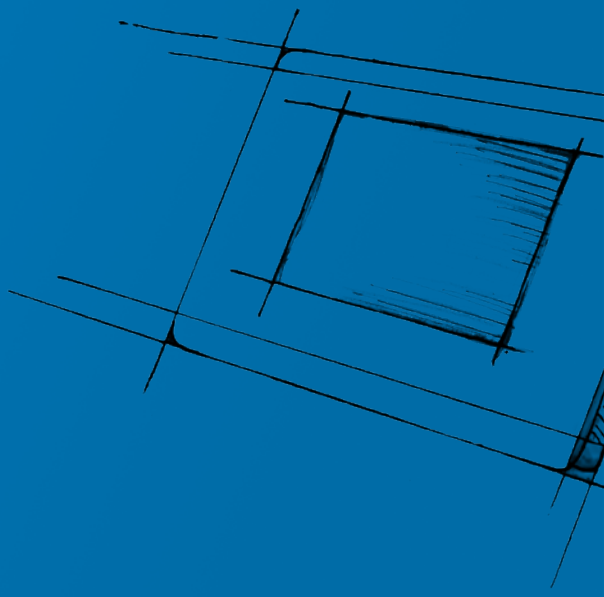
LEONARDO®

Universal and ingenious

- Cutting
- Vaporization
- Tissue shrinking
- Coagulation
- Dual wavelength laser individually selected or blended

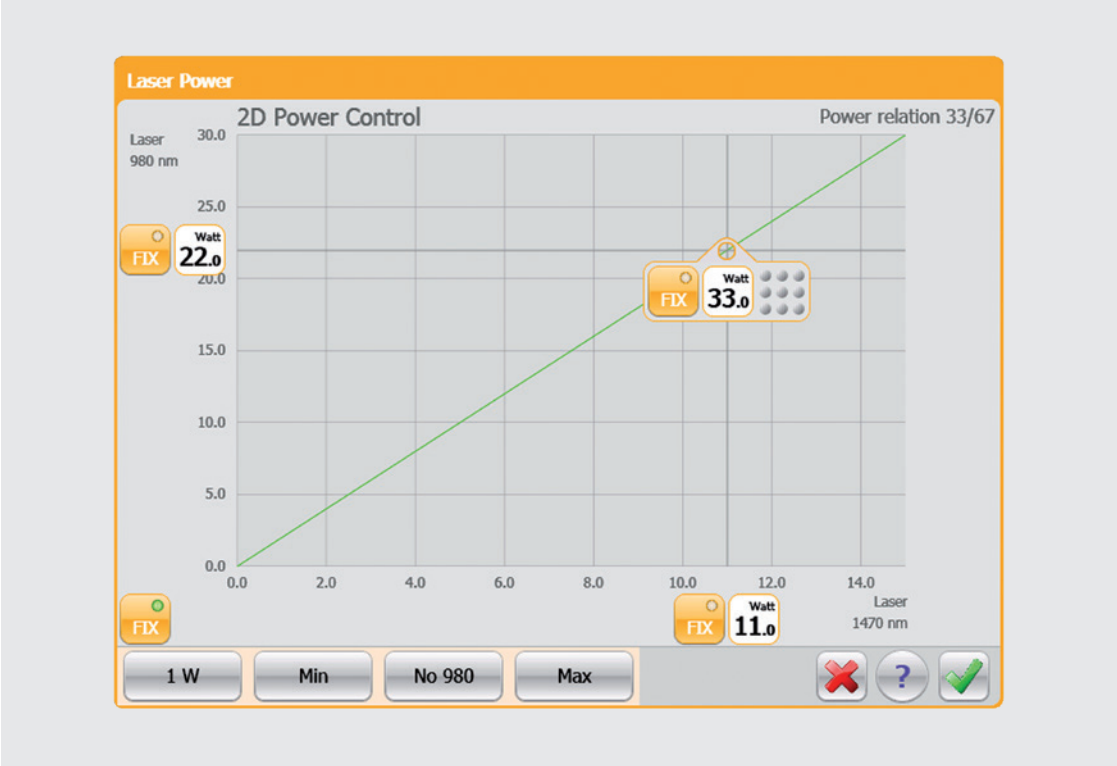
bioLITEC®

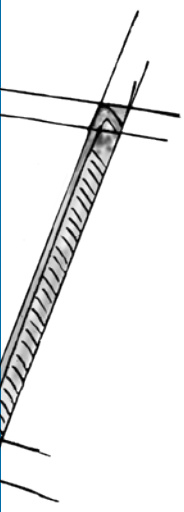
A whole new world of therapeutic applications and clinical results



biolitec® presents the LEONARDO® Laser – the most versatile and universal medical laser in the market today. This highly compact diode laser features the combination of two wavelengths, 980 nm and 1470 nm offering a variety of tissue interactions. Each wavelength can be individually selected or **blended** together to offer the perfect desired tissue effects such as incision, excision, vaporization, hemostasis and coagulation of soft tissue with contact or non-contact delivery options for open and endoscopic procedures. For the first time the clinicians can perform laser surgery selectively, with settings individually tailored to the tissue type and the desired tissue effects and thus corresponding to the therapeutic needs.

The ability to choose a wavelength mix opens a whole new world of therapeutic applications and improves both the treatment outcomes for the patients and **extends** the clinicians experience and expertise. The LEONARDO® Laser is designed to work in perfect combination with a broad spectrum of special medical fibers and application kits developed by biolitec® and its companies. biolitec® is one of the **world's most** technologically advanced suppliers of fiberoptic products. The biolitec® treatment methods are routinely performed and validated in highly respected medical centers worldwide and are the number one choice for treating a wide variety of diseases and medical conditions.





2D Power Control

LEONARDO®'s intuitive 2D Power Control enables the user to choose a combination of different wavelengths and power settings with a simple touch of the screen.

New Fiber Connector

The new fiber connector facilitates to plug the fiber into the laser. It is equipped with an electronic signature for increased patient safety. It prevents usage beyond the product's lifetime and hazards caused by inserting unsuitable fibers to the laser.

Advantages

Versatile and universal

- Broad spectrum of minimally invasive therapeutic laser applications

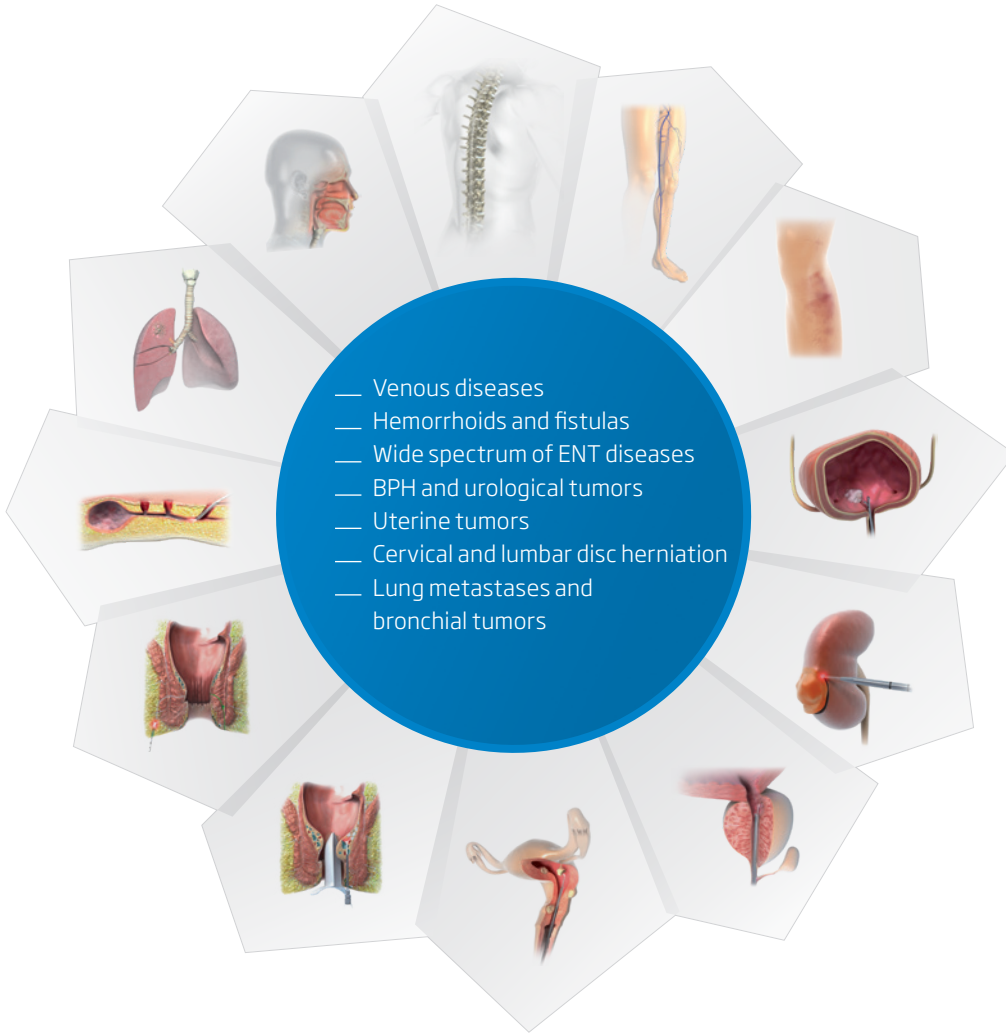
User-Friendly

- Intuitive use with touch screen and fast set-up
- Selection between pre-set modes or individualized settings
- Choice between green or red aiming beam

Economic

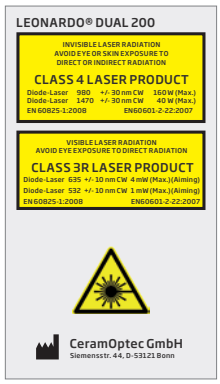
- Two wavelength in one compact and space-saving laser system
- Multidisciplinary use
- Low-maintenance and reliable laser diodes

Special medical fibers and application kits available for minimally invasive laser therapies of:



LEONARDO®

Model	**LEONARDO® DUAL 45**
REF	SL980+1470nm45W
Wavelength	980 nm and 1470 nm
Power max.	45 Watt (1470 nm / 15 Watt + 980 nm / 30 Watt) separately adjustable
Fiber diameter	≥ 360 µm
Aiming beam	532 nm and 635 nm, green 1 mW, red 4 mW, user controlled intensity
Treatment mode	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode
Pulse duration / -break	0.01 – 60 sec / 0.01 – 60 sec
Power supply	110 - 240 VAC, 50 / 60 Hz, 450 VA
Dimensions (H × W × D)	approx. 28 cm × 37 cm × 9 cm
Weight	approx. 8.5 kg



Model	**LEONARDO® DUAL 100**
REF	SL980+1470nm100W
Wavelength	980 nm and 1470 nm
Power max.	100 Watt (1470 nm / 15 Watt + 980 nm / 85 Watt) separately adjustable
Fiber diameter	≥ 360 µm
Aiming beam	532 nm and 635 nm, green 1 mW, red 4 mW, user controlled intensity
Treatment mode	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode
Pulse duration / -break	0.01 – 60 sec / 0.01 – 60 sec
Power supply	110 - 240 VAC, 50 / 60 Hz, 850 VA
Dimensions (H × W × D)	approx. 28 cm × 37 cm × 9 cm
Weight	approx. 8.5 kg

Model	**LEONARDO® DUAL 200**
REF	SL980+1470nm200W
Wavelength	980 nm and 1470 nm
Power max.	200 Watt (1470 nm / 40 Watt + 980 nm / 160 Watt) separately adjustable
Fiber diameter	≥ 360 µm
Aiming beam	532 nm and 635 nm, green 1 mW, red 4 mW, user controlled intensity
Treatment mode	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode
Pulse duration / -break	0.01 – 60 sec / 0.01 – 60 sec
Power supply	110 - 240 VAC, 50 / 60 Hz, 850 VA
Dimensions (H × W × D)	approx. 20 cm × 37 cm × 26 cm
Weight	approx. 15 kg

Why did we name our laser LEONARDO®?

Leonardo was born in Vinci, near Florence, in 1452. He showed early interest in many different subjects and a precocious talent for drawing. During his career he worked for many illustrious men of his age: the Medici family in Florence, Ludovico il Moro and Francesco Sforza in Milan, Louis XII and Francis I of France and many others.
Along with his profession, he applied himself in countless different fields. He studied natural sciences firsthand, discovering new (at that time) phenomena in geology, astronomy, botany, hydraulics, etc. He was a prolific inventor: he produced projects, prototypes and concepts for many applications as the parachute, a surface-supplied diving suit, different artillery pieces, warships, a tank, a rudimentary helicopter, a bicycle and many more. Leonardo da Vinci was also hired as an engineer, mainly for hydraulic and military structures and applications.
His contribution to human anatomy is of the highest importance: at his time anatomy and natural sciences in general were approached in a purely theoretical fashion, by studying the texts of the ancient authors. Da Vinci on the contrary studied the human body through the dissection of corpses (a forbidden practice in that period) and produced illustrations of the different apparatuses, which have been used in anatomy texts until recent times. Due to this extraordinary eclecticism, **Leonardo da Vinci is universally regarded as the epitome of the universal genius.**

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bio LITEC®

All fibers are free of latex and DEHP. Our fibers are single use products (unless otherwise indicated) delivered sterile for immediate use.

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9.2 General specifications for all LEONARDO® models

Numerical aperture	NA = 0.25 (or higher)
Fiber connector	Modified SC
Treatment mode	Continuous (CW) / Pulse
Pulse duration	Variable: 0.01 to 60.0 seconds
Power control	Integrated power control
Aiming beam; power	635nm ± 10nm; 4mW (max) 532nm ± 10nm; 1mW (max)
Laser class according to 60825-1	4
Class of device according to 60601-1	IIb
Cooling	Air cooling fan
Storage and transport conditions	Temperature: -10 to +40°C Rel. humidity: <80% RH non condensing Atmospheric pressure: 700 to 1100 hPa
Operating conditions	Temperature: +10 to +25°C Rel. humidity: < 50% RH non condensing Atmospheric pressure: 760 to 1100 hPa
Dimension housing (HxWxD)	Leonardo® 1470: 275 mm x 370 mm x 85 mm Leonardo® Dual45: 275 mm x 370 mm x 85 mm Leonardo® Dual100: 275 mm x 370 mm x 85 mm Leonardo® Dual200: 200 mm x 370 mm x 260 mm
Weight	Leonardo® 1470: app.8,5 kg Leonardo® Dual45: app.8,5 kg Leonardo® Dual100: app.8,5 kg Leonardo® Dual200: app.15 kg
Applied part	Type B
Mains isolation	Disconnection from mains is done by mains switch

alsa®
bologna

CS200 - CS200LC - CS900LC

ASPIRATORI DI FUMO
SMOKE EVACUATORS

CS200
open surgery

CS900LC
operating theatre
open surgery – laparoscopy

CS200LC
laparoscopy

CSQ ISO 9001 9120.ALSA
IQNet IT - 1231
CSQ MED ISO 13485 9124.ALS2

CE 0051

CS - ASPIRATORI DI FUMO

Gli aspiratori di fumo **CS** sono degli aspiratori con caratteristiche assolutamente innovative, realizzati per aspirare e filtrare i fumi prodotti durante ogni tipo di procedura elettrochirurgica eliminando cattivi odori o rischi batteriologici, e risolvendo il problema, ricorrente durante le procedure laparoscopiche, della visione ottimale del campo operatorio.

Il **CS200**, dotato di un gruppo aspirante elettrico ad altissima portata e media rumorosità completo anche della funzione *TURBO - altissima aspirazione,* è il modello base, ideale per l'uso ambulatoriale (ginecologia, chirurgia minore, laser) con collegamento allo speculum, con sistemi di aspirazione sul manico porta-elettrodi, con tubazione fissa posizionata sul punto di intervento.

Il **CS900LC** è il modello più completo della serie dotato di un gruppo aspirante elettrico silenziosissimo, con alta portata per usi generali, e bassa per laparoscopia.

Il CS200LC è il modello specifico per le procedure laparoscopiche.

CARATTERISTICHE TECNICHE

CARATTERISTICHE TECNICHE GENERALI

- ***Microprocessor Control System*** - Controllo del funzionamento mediante microprocessore con auto-check all'accensione.
- ***Filtro a tre stadi*** - Uno antibatterico monouso tipo HEPA con efficienza pari a 99,99999% per particelle con Ø 0,3 micron, uno antibatterico tipo ULPA con efficienza pari a 99,99999% per particelle con Ø 0,12 micron ed uno antiodori ai carboni attivi controllato mediante microprocessore con doppia verifica (efficienza del filtro e durata massima di 50 ore), segnalazione luminosa di allarme e blocco del funzionamento alla prima accensione dopo l'intervento del circuito di controllo.
- ***Automatic Start/Stop Sensing System*** - Attivazione/spegnimento automatico dell'aspirazione ogni volta che si attiva l'elettrobisturi mediante un sensore senza contatto che elimina la necessità sia di specifici collegamenti all'elettrobisturi sia di un eventuale comando a pedale.
- ***Ritardo di Spegnimento Programmabile*** - Regolazione del ritardo di spegnimento dell'aspirazione da 0 fino ad almeno 30 sec. al fine di permettere la completa eliminazione dei fumi.
- ***Comando a pedale di attivazione*** - Pneumatico, stagno, antiesplosione per sala operatoria IPX7/AP/APG (standard solo per i modd. CS200LC e CS900LC).
- ***Involucro*** - Metallico verniciato.
- ***Raffreddamento*** - Per convezione, senza ventilatore.
- ***Classificazione IEC 60601-1*** - Classe I, tipo BF (dispersione nell'involucro, minore di 25 microA - dispersione nel paziente: assente)
- ***Norme di Sicurezza*** - Apparecchi conformi a norme IEC 601-1.
- ***Classe e Certificato CE (93/42+2007/47)***: IIA, CE0051-nr. 187/MDD.

CARATTERISTICHE TECNICHE CS200

- ***Gruppo aspirante*** - Rotativo non lubrificato - Portata standard 600 lt/min / TURBO 800 lt/min - Vuoto massimo: 110 mmHg.
- ***Regolazione aspirazione*** - Elettronica con anche funzione Turbo-altissima aspirazione. Comando rotativo e indicatore luminoso.
- ***Alimentazione di rete/Assorbimento/Fusibili/Interruttore di rete*** - 110 o 230V-50/60 Hz / 650 VA / 2x5A / Bipolare verde
- ***Dimensioni e Peso*** - cm. 38x44x18, Kg. 10,5.

CARATTERISTICHE TECNICHE CS900LC

- ***Gruppo aspirante*** - Rotativo lubrificato - Portata: 100 lt/min - Vuoto massimo: 720/730 mmHg.
- ***Regolazione aspirazione*** - Comando rotativo con scala graduata.
- ***Alimentazione di rete/Assorbimento/Fusibili/Interruttore di rete*** - 110 o 230V-50/60 Hz / 460 VA / 2x3,15A / Bipolare verde
- ***Dimensioni e Peso*** - cm. 38x44x18, Kg. 18,5.

CARATTERISTICHE TECNICHE CS200LC

- ***Gruppo aspirante*** - A membrana - Portata: 10 lt/min - Vuoto massimo: 600 mmHg.
- ***Regolazione aspirazione*** - Automatica.
- ***Alimentazione di rete/Assorbimento/Fusibili/Interruttore di rete*** - 110 o 230V-50/60 Hz / 170 VA / 2x0,4A / Bipolare verde
- ***Dimensioni e Peso*** - cm. 38x30x14, Kg. 7,5.

ACCESSORI STANDARD

Modello CS200

1 - Gruppo filtri (antibatterico interno MAX2, antibatterico esterno DE19, antiodori a carboni attivi SCA).
1 - Tubazione non sterile **T19-1.5** (per sistema fisso di aspirazione o prolunga di **TS/T-5S**).
1 - Tubazione non sterile **TS/T-5S**, l. 5mt

Modello CS900LC

1 - Gruppo filtri (antibatterico interno MAX2, antibatterico esterno DE19, antiodori a carboni attivi SCA).
1 - Tubazione non sterile **T19-1.5** (per sistema fisso di aspirazione o prolunga di **T11-1.8**).
1 - Tubazione sterile monouso **T11-1.8** per collegamento a speculum, a set di aspirazione per manico porta elettrodi, a manico sterile con aspirazione, al trocar in laparoscopia.

Modello CS200LC

1 - Gruppo filtri (antibatterico interno MAX2, antibatterico estreno DE19, antiodori a carboni attivi SCA).
1 - Tubazione non sterile **T19-1.5** (per sistema fisso di aspirazione o prolunga di **T11-1.8**).
1 - Tubazione sterile monouso **T11-1.8** per collegamento a speculum, a set di aspirazione per manico porta elettrodi, a manico sterile con aspirazione, al trocar in laparoscopia.

ELENCO GENERALE ACCESSORI

Filtri interni.
SCA - Filtro antiodore a carboni attivi. (*)
MAX2 - Filtro antibatterico/antivirale tipo ULPA. (*)

Filtro esterno sterile per tubazione di aspirazione.
DE19 - Filtro sterile per tubazione di aspirazione. (*)

Tubazione di aspirazione sterile monouso.
T11-1.8 -Tubazione sterile monouso, l. mt 1,8 – Ø 11 mm. (*)

Tubazione di estensione per T11-1.8 o TS/T-5S, o di aspirazione con GRA.
T19-1.5 - Tubazione di estensione, l. mt 1,5 – Ø 19 mm. (*)

Tubazione di aspirazione in silicone autoclavabile.
TS/T-5S - Tubazione, l. mt.5, Ø 7x12 con raccordo di collegamento all'apparecchio.

Set sterile monouso per laparoscopia o usi generali.
STERSET - Filtro antibatterico con tubazione l. mt. 5 ed attacco luer lock. (*)

Set di aspirazione per manipoli, Manipoli portaelettrodi con sistema di aspirazione, Tubazioni di collegamento.
Disponibili su richiesta.

Carrello, braccio mobile di sostegno tubazione e sistema rigido di aspirazione.
H23/SE - Carrello con 3 piani, cm 50x50x80, ruote antistatiche, due con freni.
EV/A - Braccio mobile per sistema rigido di aspirazione **GRA**.
GRA - Sistema rigido di aspirazione (per uso ambulatoriale).

CS - SMOKE EVACUATORS

The smoke evacuators **CS** are innovative suction units, which have been designed to evacuate and filter the smoke produced during all the electrosurgical procedures, by eliminating the bad smells or the bacteriological risks, and by solving the very common problem of the visual field during the laparoscopic procedures.

The **CS200** is equipped with an electric suction group at high flow and medium noise; moreover, it has got the function *TURBO - high suction*. It represents the basic model, which is ideal for outpatient (gynaecology, minor surgery, laser), with speculum connection, with aspiration systems on the electrodes-holder handle, and with fixed tubing placed on the intervention point.

The **CS900LC** is the most complete model of the series, which is equipped with an electric suction group at low noise, and high flow for general use and low flow for laparoscopy.

The **CS200LC** is the specific model for the laparoscopic procedures.

TECHNICAL CHARACTERISTICS

GENERAL TECHNICAL CHARACTERISTICS

- ***Microprocessor Control System*** - Functioning control through micro-processor, with auto-check at the switching-on.
- ***Three Stages Filter*** - One disposable antibacterial HEPA type with a total efficiency 99.99999% for Ø 0.3 micron particles, one antibacterial ULPA type with a total efficiency 99.99999% for Ø 0.12 micron particles, and one anti-smell with active carbons - controlled by a micro-processor with double check (filter efficacy and limit time of 50 hours), luminous alarm signal and functioning block after the first switching-on before the intervention of the control circuit.
- ***Automatic Start/Stop Sensing System*** - Automatic switching on / switching off of the suction system, every time the electrosurgical unit is activated, through a non-contact sensing system which eliminates the need of both specific connections to the electrosurgical unit and a pedal.
- ***Programmable Stop Delay*** - Adjusting of the delay in the switching off of the suction system from 0 to al least 30sec, in order to completely eliminate the smoke.
- ***Switching on Pedal*** - Pneumatic, waterproof, anti-explosion, for operating theatre IPX7/AP/APG (included for the models CS200LC and CS900LC only).
- ***Enclosure*** - Metallic and painted.
- ***Cooling*** – By convection, no fan.
- ***Classification IEC 60601-1*** - Class I, type BF (leakage to the enclosure: less than 25microA; leakage to the patient: absent).
- ***Safety Rules*** - The units meet IEC 601-1 Safety Rules.
- ***Class and EC Certificate (93/42+2007/47)***: IIA, CE0051-nr. 187/MDD.

TECHNICAL CHARACTERISTICS CS200

- ***Suction Group*** - Rotative, non lubricated - Flow: standard 600 lt/min / TURBO 800 lt/min - Max. vacuum: 110 mmHg.
- ***Suction Regulation*** - Electronic, with function *Turbo - high suction*. Rotative control with visual bar-led
- ***Mains / Absorption / Fuses / Switch*** - 110 or 230V-50/60Hz / 650VA / 2x5A / Bipolar, green.
- ***Dimensions and Weight*** - cm. 38x44x18, Kg. 10.5

TECHNICAL CHARACTERISTICS CS900LC

- ***Suction Group*** - Rotative, lubricated - Flow: 100 lt/min - Max. vacuum: 720/730 mmHg.
- ***Suction Regulation*** - Rotative control, with graduated scale.
- ***Mains / Absorption / Fuses / Switch*** - 110 or 230V-50/60Hz / 460VA / 2x3, 15A / Bipolar, green.
- ***Dimensions and Weight*** - cm. 38x44x18, Kg. 18.5

TECHNICAL CHARACTERISTICS CS200LC

- ***Suction Group*** - Membrane - Flow: 10 lt/min - Max. vacuum: 600 mmHg.
- ***Suction Regulation*** - Automatic.
- ***Mains / Absorption / Fuses / Switch*** - 110 or 230V-50/60Hz / 170VA / 2x0,4A / Bipolar, green.
- ***Dimensions and Weight*** - cm. 38x30x14, Kg. 7.5

STANDARD ACCESSORIES

Model CS200

1 - Filter group (internal antibacterial MAX2, external antibacterial DE19, anti-smell with active carbons SCA).
1 - Non sterile tubing **T19-1.5** (for a fixed suction system, or extension of **TS/T-5S**).
1 - Non sterile tubing **TS/T-5S**, l. mt 5.

Model CS900LC

1 - Filter group (internal antibacterial MAX2, external antibacterial DE19, anti-smell with active carbons SCA).
1 - Non sterile tubing **T19-1.5** (for a fixed suction system, or extension of **T11-1.8**).
1 - Disposable sterile tubing **T11-1.8** for the connection to the speculum, to the suction set for the electrodes-handle, to the sterile handle with suction system and to the trocar in laparoscopy.

Model CS200LC

1 - Filter group (internal antibacterial MAX2, external antibacterial DE19, anti-smell with active carbons SCA).

GENERAL LIST OF ACCESSORIES

Internal Filters.
SCA - Anti-smell filter with active carbons. (*)
MAX2 - Antibacterial/Antiviral filter ULPA type. (*)

External Sterile Filter for suction tubing.
DE19 - Sterile filter for suction tubing. (*)

Disposable sterile suction tubing.
T11-1.8 - Disposable sterile tubing, l. mt1,8 - Ø 11mm. (*)

Extension tubing for T11-1.8 or TS/T-5S, or suction tubing with GRA.
T19-1.5 - Extension tubing, l. mt1,5 - Ø 19mm. (*)

Suction tubing in autoclavable silicone.
TS/T-5S - Tubing, l. mt 5 and Ø 7x12 with connection to the unit.

Disposable sterile set for laparoscopy or general applications.
STERSET - Antibacterial filter with tubing 5mt. long and luer lock connection. (*)

Aspiration set for handles, Electrodes-holder handles with suction system, Connection tubings.
Available on request.

Trolley, mobile arm for the tubing, and rigid suction system.
H23/SE - Trolley with 3 shelves, 50x50x80 cm, antistatic wheels, 2 with brakes.
EV/A - Mobile arm for rigid suction system **GRA**.
GRA - Rigid suction system (for out-patient treatment).

CS - EVACUATEURS DE FUMÉE

Les évacuateurs de fumée **CS** représentent des aspirateurs avec des caractéristiques tout à fait innovantes, conçus pour aspirer et filtrer les fumées produites pendant toutes procédures électro-chirurgicales, en éliminant les mauvaises odeurs et les risques bactériologiques. En plus, ils résolvent le problème, très commun pendant les procédures laparoscopiques, d'avoir une bonne vision du camp opératoire.

Le **CS200**, équipé d'un groupe d'aspiration électrique avec un débit très élevé et un niveau de rumeur moyen, possède aussi la fonction TURBO – aspiration très élevée. Il s'agit du modèle « base », idéal pour le cabinet du médecin (gynécologie, petite chirurgie, laser), avec une connexion directe pour le spéculum, avec des systèmes d'aspiration sur le manche porte-électrodes, avec un tuyau fixe positionné sur le point exact d'intervention.

Le CS900LC est le modèle le plus complet de la série: il est équipé d'un groupe d'aspiration électrique très silencieux, avec un débit très élevé pour les applications générales, et un débit plus bas pour laparoscopie.

Le CS200LC est idéal pour résoudre les problèmes de l'aspiration pendant les procédures laparoscopiques.

CARACTERISTIQUES TECHNIQUES

CARACTERISTIQUES TECHNIQUES GENERALES

- ***Système de Contrôle Microprocesseur*** - Vérifie du fonctionnement grâce à un microprocesseur doué de système d'autocontrôle au moment de l'activation.
- ***Filtre à Trois Phases*** - L'un antibactérien disposable type HEPA avec une performance totale de 99,99999% pour des particules de Ø 0,3 micron, l'un antibactérien type ULPA avec une performance totale de 99,99999% pour des particules de Ø 0,12 micron, et l'un anti-odeurs avec les charbons actifs, contrôlé par un microprocesseur avec une double vérifie (efficacité du filtre et temps limite de 50 heures), un signal lumineux d'alarme, et le blocage du fonctionnement à la première activation après l'intervention du circuit de contrôle.
- ***Système Automatique Sensible "Start/Stop"*** - Activation/Arrêt automatique de l'aspiration chaque fois que le bistouri est activé par un senseur sans contact, ce qui élimine le besoin d'avoir des connexions spécifiques au bistouri ainsi qu'un commandement à pédale.
- ***Retard d'Arrêt Programmable*** - Réglage du retard dans l'arrêt de l'aspiration de 0 à au moins 30sec., ce qui permet l'élimination complète des fumées.
- ***Commandement à Pédale pour l'Activation*** - Pneumatique, étanche, anti-explosion, pour la salle opératoire IPX7/AP/APG (déjà inclus pour les modèles CS200LC et CS900LC).
- ***Châssis*** - Métallique et peint avec vernis.
- ***Classification IEC 60601-1*** - Classe I, type BF (dispersion dans le châssis: inférieure à 25microA - dispersion dans le patient: absente).
- ***Normes de Sécurité*** - Appareils conformes aux normes IEC 601-1.
- ***Classe et Certificat CE (93/42+2007/47)***: IIA, CE0051-nr. 187/MDD.

CARACTERISTIQUES TECHNIQUES CS200

- ***Groupe Aspirant*** - Rotatif non lubrifié – Débit: standard 600 lt/min / TURBO 800 lt/min - Vide Maximum: 110 mmHg.
- ***Réglage de l'Aspiration*** - Electronique, avec fonction *TURBO – aspiration très élevée*. Commandement rotatif de contrôle, avec signal lumineux;
- ***Alimentation de réseau/Absorption/Fusibles/Interrupteur de réseau*** - 110 ou 230V / 50/60Hz / 650VA / 2x5A / Bipolaire, vert.
- ***Dimensions et Poids*** - cm. 38x44x18, Kg. 10,5.

CARACTERISTIQUES TECHNIQUES CS900LC

- ***Groupe Aspirant*** - Rotatif lubrifié – Débit: 100 lt/min - Vide Maximum: 720/730 mmHg.
- ***Réglage de l'Aspiration*** - Commandement rotatif de contrôle, avec échelle graduée.
- ***Alimentation de réseau/Absorption/Fusibles/Interrupteur de réseau*** - 110 ou 230V - 50/60 Hz / 460VA / 2x3,15A / Bipolaire, vert.
- ***Dimensions et Poids*** - cm. 38x44x18, Kg. 18,5.

CARACTERISTIQUES TECHNIQUES CS200LC

- ***Groupe Aspirant*** - À membrane – Débit: 10 lt/min - Vide Maximum: 600 mmHg.
- ***Réglage de l'Aspiration*** - Automatique.
- ***Alimentation de réseau/Absorption/Fusibles/Interrupteur de réseau*** - 110 ou 230V / 50/60 Hz / 170VA / 2x0,4A / Bipolaire, vert.
- ***Dimensions et Poids*** - cm. 38x30x14, Kg. 7,5.

ACCESSOIRES STANDARD

Modèle CS200

1 - Groupe filtres (antibactérien interne MAX2, antibactérien externe DE19, anti-odeurs avec les charbons actifs SCA).
1 - Tuyau non stérile **T19-1.5** (pour le système fixe d'aspiration ou prolongateur pour **TS/T-5S**).
1 - Tuyau non stérile **TS/T-5S**, l. mt5.

Modèle CS900LC

1 - Groupe filtres (antibactérien interne MAX2, antibactérien externe DE19, anti-odeurs avec les charbons actifs SCA).
1 - Tuyau non stérile **T19-1.5** (pour le système fixe d'aspiration ou prolongateur pour **T11-1.8**).
1 - Tuyau stérile disposable **T11-1.8** pour connexion à spéculum, au jeu d'aspiration pour manche porte-électrodes, au manche stérile avec aspiration, au trocar pour laparoscopie.

Modèle CS200LC

1 - Groupe filtres (antibactérien interne MAX2, antibactérien externe DE19, anti-odeurs avec les charbons actifs SCA).

LISTE GENERALE DES ACCESSOIRES

Filtres Internes.
SCA - Filtre anti-odeurs avec les charbons actifs. (*)
MAX2 - Filtre antibactérien / antiviral type ULPA. (*)

Filtre extérieur stérile pour le tuyau d'aspiration.
DE19 - Filtre stérile antibactérien / antiviral pour le tuyau d'aspiration. (*)

Tuyau d'aspiration stérile disposable.
T11-1.8 - Tuyau stérile disposable, l. mt1,8 – Ø 11mm. (*)

Tuyau d'extension pour T11-1.8 ou TS/T-5S, ou d'aspiration avec GRA.
T19-1.5 - Tuyau d'extension, l. mt1,5 – Ø 19mm. (*)

Tuyau d'aspiration en silicone autoclavable.
TS/T-5S - Tuyau, l. mt5 et Ø 7x12mm avec raccord de connexion à l'appareil.

Jeu stérile disposable pour laparoscopie ou applications générales.
STERSET - Filtre antibactérien avec tuyau de 5mt. de long et connexion luer lock. (*)

Jeu d'aspiration pour les manches, Manches porte-électrodes monopolaires avec système d'aspiration, Tuyaux de connexion.
Disponibles sur requête.

Chariot, bras mobile de soutient, tuyau et système rigide d'aspiration.
H23/SE - Chariot avec 3 étagères, 50x50x80 cm, roues antistatiques, 2 avec freins.
EV/A - Bras mobile pour le système rigide d'aspiration **GRA**.
GRA - Système rigide d'aspiration (pour le cabinet du médecin).

CS - EVACUADORES DE HUMO

Los evacuadores de humo **CS** son aspiradores con características completamente nuevas, fabricados para aspirar y filtrar los humos producidos durante cualquier tipo de intervención electro-quirúrgica, eliminando malos olores o riesgos bacteriológicos, resolviendo el problema común en las intervenciones laparoscópicas optimizando la visión del campo operatorio.

El **CS200** dotado de un grupo de aspiración eléctrico de alta capacidad y silencioso, completo también de función *TURBO (alta aspiración)*, es el modelo base, idóneo para ambulatorios (ginecología, pequeña cirugía, y laser), con conexión al espéculo, con sistemas de aspiración insertados en el mango porta-eléctrodos, con tubos fijos posicionados sobre el punto de intervención.

El **CS900LC** es el modelo más completo de la serie, dotado de un grupo de aspiración eléctrico muy silencioso, con alto flujo para las aplicaciones generales, y bajo flujo para laparoscopía.

El **CS200LC** es idóneo para los problemas de aspiración durante los procedimientos laparoscópicos.

CARACTERISTICAS TECNICAS

CARACTERISTICAS TECNICAS GENERALES

- ***Microprocesador control System*** - Control del funcionamiento mediante un micro-procesador con auto-check durante el encendido.
- ***Filtro de tres fases*** - Uno antibacteriano desechable de tipo HEPA con una eficacia total de 99,99999% por partículas de Ø 0,3 micron, uno antibacteriano de tipo ULPA, con una eficacia total de 99,99999% por partículas de Ø 0,12 micron, y uno anti-olores de carbón activo, controlado mediante micro-procesador de doble control (eficacia del filtro y tiempo límite de 50 horas), señal luminosa de alarma, y bloqueo del funcionamiento al primer encendido después de la intervención del circuito de control.
- ***Automatic Start/Stop Sensing System*** - Encendido/Apagado automático del sistema de aspiración cada vez que se activa el bisturí mediante un sensor sin contacto que elimina la necesidad de tener conexiones específicas con el bisturí, de un eventual mando de pedal.
- ***Retardo de Apagado Programable*** - Regulación del retraso del apagado de la aspiración desde 0 hasta al menos 30sec., para permitir la eliminación completa de los humos.
- ***Mando de pedal de activación*** - Neumático, hermético, anti-explosión, para el uso en quirófano IPX7/AP/APG (incluído solamente para los modelos CS200LC y CS900LC).
- ***Chasis*** - Metálico y barnizado.
- ***Enfriamiento*** - por calefacción sin ventilador.
- ***Clasificación IEC 60601-1*** - Clase I, tipo BF (dispersión en el chasis: menor de 25microA - dispersión en el paciente: nula).
- ***Normas de Securidad*** - Equipos conforme a normas IEC 601-1.
- ***Clase y Certificado CE (93/42+2007/47)***: IIA, CE0051-nr. 187/MDD.

CARACTERISTICAS TECNICAS CS200

- ***Grupo de aspiración*** - Rotatorio, no lubrificado – Caudál: estandar 600 lt/min / TURBO 800 lt/min - Vacío máximo: 110 mmHg.
- ***Regulación de la aspiración*** - Electrónica, con función *TURBO – alta aspiración*. Mando rotatorio e indicador luminoso.
- ***Alimentación de red/Absorción/Fusibles/Interruptor de red*** - 110 o 230V - 50/60Hz / 650VA / 2x5A / Bipolar verte.
- ***Dimensiones y Peso*** - cm. 38x44x18, Kg. 10,5.

CARACTERISTICAS TECNICAS CS900LC

- ***Grupo de aspiración*** - Rotatorio lubrificado - Caudál: 100 lt/min - Vacío máximo: 720/730 mmHg.
- ***Regulación de la aspiración*** - Mando rotatorio con escala graduada.
- ***Alimentación de red/Absorción/Fusibles/Interruptor de red*** - 110 o 230V-50/60Hz / 460VA / 2x3,15A / Bipolar verte.
- ***Dimensiones y Peso*** - cm. 38x44x18, Kg. 18,5.

CARACTERISTICAS TECNICAS CS200LC

- ***Gruppo de aspiración*** - A membrana - Caudál: 10 lt/min - Vacío máximo: 600 mmHg.
- ***Regulación de la aspiración*** - Automática.
- ***Alimentación de red/Absorción/Fusibles/Interruptor de red*** - 110 o 230V-50/60Hz / 170VA / 2x0,4A / Bipolar verte
- ***Dimensiones y Peso*** - cm. 38x30x14, Kg. 7,5.

ACCESORIOS ESTANDAR

Modelo CS200

1 - Grupo filtros (antibactericida interno MAX2, antibactericida externo DE19, anti-olores de carbones activos SCA).
1 - Tubos no estériles **T19-1.5** (para sistema fijo de aspiración o alargador de **TS/T-5S**).
1 - Tubos no estériles **TS/T-5S**, l. 5mt.

Modelo CS900LC

1 - Grupo filtros (antibactericida interno MAX2, antibactericida externo DE19, anti-olores de carbones activos SCA).
1 - Tubos no estériles **T19-1.5** (para sistema fijo de aspiración o alargador de **T11-1.8**).
1 - Tubos estériles desechables **T11-1.8** para la conexión con espéculo, con juego de aspiración para mango porta-eléctrodos, con mango estéril de aspiración y con trocar en laparoscopia.

Modelo CS200LC

1 - Grupo filtros (antibactericida interno MAX2, antibactericida externo DE19, anti-olores de carbones activos SCA).

LISTA GENERAL DE ACCESORIOS

Filtros Internos
SCA - Filtro anti-olores de carbón activo. (*)
MAX2 - Filtro antibactericida/antiviral de tipo ULPA. (*)

Filtro externo estéril para tubos de aspiración.
DE19 - Filtro estéril antibactericida/antiviral para tubos de aspiración. (*)

Tubo de aspiración estéril desechable.
T11-1.8 -Tubo estéril desechable, l. 1,8mt – Ø 11mm. (*)

Tubo de extensión para T11-1.8 o TS/T-5S, o de aspiración con GRA.
T19-1.5 - Tubo de extensión, l. 1,5mt – Ø 19mm. (*)

Tubo de aspiración en silicona autoclavable.
TS/T-2.5 - Tubo, l. 5mt y Ø 7x12mm con conexión al equipo.

Juego estéril desechable para laparoscopia o aplicaciones generales.
STERSET - Filtro antibactericida con tubo largo 5mt. y conexión luer lock. (*)

Juego de aspiración para mangos, Mangos porta-eléctrodos monopolares con sistema de aspiración, Tubos de conexión.
Disponibles a pedido.

Carro, brazo móvil de apoyo, tubos y sistema rígido de aspiración.
H23/SE - Carro con 3 estantes, cm. 50x50x80, ruedas antiestáticas, dos con freno.
EV/A - Brazo móvil para sistema rígido de aspiración **GRA**.
GRA - Sistema rígido de aspiración (para ambulatorio).

alsa apparecchi medicali s.r.l.
Via C. Bonazzi, 16
40013 CASTEL MAGGIORE (BO) - ITALIA
Tel. +39 051 70 01 01 (r.a.) Fax +39 051 70 21 82
www.alsamed.com
alsa@alsamed.com

- È fatta riserva di apportare tutte le varianti a miglioria che si riterranno opportune, senza preavviso.
- The manufacturer has the right to change the specifications to improve the quality of the products without notice.
- La maison constructrice se reserve le droit d'apporter toutes les modifications nécessaries pour améliorer ses produits, sans préavis.
- El productor se reserva el derecho de aportar las modificaciones necesarias sin aviso.

(*) Possono non essere certificati CE0051.

CS/REV G - Edizione 06/2020

EG-Konformitätserklärung
EC Declaration of Conformity

gemäß EG-Richtlinie 93/42/EWG inkl. der Änderung 2007/47/EG
according to EC directive 93/42/EEC incl. Amendment 2007/47/EC

Produkt *Product*	**Leonardo®**, siehe Anhang „Produkte" ***Leonardo®**, see Appendix „Products"*
Klassifizierung *Classification*	IIb gemäß EG-Richtlinie 93/42/EWG Anhang IX; Regel 9. *IIb according to EC directive 93/42/EC Annex IX, rule 9.*
UMDNS-Nummer UMDNS-No	17-447
GMDN-Nummer GMDN-No	60341
Hersteller **Manufacturer**	CeramOptec GmbH Siemensstrasse 44 53121 Bonn Germany

Hiermit erklären wir die Konformität der im Anhang „Produkte" gelisteten Produkte gemäß EG-Richtlinie 93/42/EWG Anhang I (mit den anwendbaren harmonisierten Normen) sowie Anhang II (ohne Abschnitt 4).
We hereby declare the conformity of products listed in appendix „Products" according to EC directive 93/42/EC Annex I (including all applicable harmonized standards) and Annex II (w/o section 4).

Applicable standards:

EN 1041:2008
EN ISO 14971: 2012
EN ISO 15223-1: 2016 (Corrected Version 2017-03)
EN 60601-1:2006+A1:2013
EN 60601-1-2:2015
EN 60601-6:2010+A1:2015
EN 60601-2-22:2013
EN 62304:2006+A1:2015
EN 62366-1: 2016
IEC 62366-1: 2016
EN 60825-1:2007
EN 60825-1:2014

Benannte Stelle *Notified Body*	**Kiwa Meyer** (Kennnummer 1984) İTOSB 9. Cad. No:15 Tepeören Tuzla İstanbul Türkiye
EG-Zertifikat *EC-Certificate*	1984-MDD-16-372 gültig bis 12.03..2024 *1984-MDD-16-372 valid until 12.03.2024*

Ceramoptec

Gültigkeit dieser
EG-Konformitätserklärung 25.03.2021
Expiring date of this
Declaration of Conformity

Bonn, 25.03.2019

.....
Director, Dr. Roland Dreschau

Anhang PRODUKTE
Appendix PRODUCTS

REF	Produktname / *product name*
LL980+1470nm45W	Leonardo® DUAL 45
LL1470nm15W	Leonardo® 1470
LL980+1470nm100W	Leonardo® DUAL 100

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CERTIFICATO N. / *CERTIFICATE N.* **9120.ALSA**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

ALSA APPARECCHI MEDICALI SRL

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, immissione in commercio, assistenza tecnica e produzione conto terzi di elettrobisturi con o senza gas ARGON e relativi accessori, aspiratori chirurgici e relativi accessori, aspiratori di fumi elettrochirurgici e relativi accessori

Design, manufacture, placing on the market, technical service and contract manufacturing of electrosurgical units with or without ARGON gas and related accessories, electrosurgical aspirators and related accessories, electrosurgical smoke evacuators and related accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1998-05-05	2019-10-31	2022-12-19

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 19

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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CISQ is the Italian Federation of management system Certification Bodies.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

ALSA APPARECCHI MEDICALI SRL

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

has implemented and maintains a

Quality Management System

for the following scope:

Design, manufacture, placing on the market, technical service and contract manufacturing of electrosurgical units with or without ARGON gas and related accessories, electrosurgical aspirators and related accessories, electrosurgical smoke evacuators and related accessories

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: ***2019 - 10 - 31***

Expires on: ***2022 - 12 - 19***

This attestation is direcly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 1231

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

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CERTIFICATO N.
CERTIFICATE N. **9124.ALS2**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

ALSA APPARECCHI MEDICALI SRL

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, immissione in commercio, assistenza tecnica e produzione conto terzi di elettrobisturi con o senza gas ARGON e relativi accessori, aspiratori chirurgici e relativi accessori, aspiratori di fumi elettrochirurgici e relativi accessori

Design, manufacture, placing on the market, technical service and contract manufacturing of electrosurgical units with or without ARGON gas and related accessories, electrosurgical aspirators and related accessories, electrosurgical smoke evacuators and related accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1998-11-30	2019-10-31	2022-12-19

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

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La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

ALSA APPARECCHI MEDICALI SRL

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

has implemented and maintains a

Quality Management System

for the following scope:

Design, manufacture, placing on the market, technical service and contract manufacturing of electrosurgical units with or without ARGON gas and related accessories, electrosurgical aspirators and related accessories, electrosurgical smoke evacuators and related accessories

Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 13485:2016

Issued on: ***2019 - 10 - 31***

Expires on: ***2022 - 12 - 19***

This attestation is direcly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 126301

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

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CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
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CERTIFICATO CE

Certificato n. 187/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:

ALSA APPARECCHI MEDICALI SRL

40013 CASTEL MAGGIORE (BO) - VIA C. BONAZZI 16 (ITA) - Italy

mantiene nello stabilimento di:

40013 CASTEL MAGGIORE (BO) - VIA C. BONAZZI 16 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Aspiratori chirurgici

Accessori per aspiratori medicali e vacuum-extractors

Accessori per elettrobisturi

Aspiratori di fumi elettrochirurgici

Elettrobisturi

Carrelli non elettrificati per apparecchi per elettrochirurgia, aspiratori di fumi elettrochirurgici e aspiratori medicali

serie e modelli indicati in Allegato

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:

10A9800405; 10A9900240; 10AA00040; 10AA00016; 10AA00060; 10AA00156; 10AA00262; 10AB00169; 10AB000170; 10AC00210; 10AE00050; 10AF00011; 10AF00032; 10AF00192; 10AG00183; 10AH00132; 10AH00244;10AI00034; 10AI00127;10AI00122; 10AJ00093; 10EL00005; COMEDCONMHDM110021912-01; 10SN00082; DM16-0007485-01; 10AN00148; 10EO00012; DM16-0007485-01; DM17-0017739-01; DM18-0029069-01; DM18-0029585-01; DM18-0031303; DM19-0046045-01.

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:	1999-05-10
Data aggiornamento:	2019-11-25
Sostituisce:	2018-11-07
Data scadenza:	2022-03-13

IMQ

CERTIFICATO CE

Certificato n. 187/MDD

Allegato

Aspiratori chirurgici

Serie: VACUMSOL Modd. VACUMSOL AS-60; VACUMSOL AS-65; VACUMSOL AS-65/H.

Serie: VORTEX-S Modd. VORTEX-S AS-200/30LT; VORTEX-S AS-200/20LT VE; VORTEX-S AS-200/30LT VE; VORTEX-S AS-200/20LT.

Serie: VORTECO Modd. VORTECO AS-100/15LT; VORTECO AS-100/20LT; VORTECO AS-100/30LT; VORTECO AS-100/30LT VE.

Serie: POLIVAC Modd. POLIVAC B4/SLT 30 1; POLIVAC B4/SLT 30 2; POLIVAC B4/SLT 30 1-EXP; POLIVAC B4/SLT 30 2-EXP; POLIVAC B4/SLT 30 P-EXP; POLIVAC B4/SLT 50 E; POLIVAC B4/SLT 30 1VE-EXP; POLIVAC B4/SLT 30 PVE-EXP.

Accessori per aspiratori medicali e vacuum-extractors

Modd. come da documento allegato "Elenco-AccAspir#A" del 29.03.2005; valido solo se provvisto del timbro IMQ.

Accessori per elettrobisturi

Modd. come da documento allegato "AccElettr-Elenco#D" del 30.03.2008; valido solo se provvisto del timbro IMQ.

Aspiratori di fumi elettrochirurgici

Serie: CS Modd. CS200; CS200LC; CS900LC

Elettrobisturi

Serie: ALSATOM Modd. ALSATOM SU 50-MPC; ALSATOM SU 100-MPC; ALSATOM SU 140-MPC; ALSATOM SU 140/D-MPC; ALSATOM SU 140/BD-MPC; ALSATOM SU 140/D-MPC (100V-60Hz).

Serie: MCDSe Modd. EXCELL 200 MCDSe; EXCELL 250 MCDSe; EXCELL 350 MCDSe; EXCELL 400 MCDSe; EXCELL 250/A MCDSe; EXCELL 400/A MCDSe.

Serie: NHP Modd. EXCELL NHP 250/D; EXCELL NHP 350/D; EXCELL NHP 400/D; EXCELL NHP 250/DA; EXCELL NHP 400/DA; EXCELL NHP ENDOMED.

Mod. MB 140-PRO
Marca ALCYON

Modd. BIPOLAR HF 100; BIPOLAR HF 140.
Marca BUTTERFLY ITALIA

Serie: NHP/T Modd. EXCELL NHP/T-400; EXCELL NHP/T-200; EXCELL NHP/TA-400; EXCELL NHP/TA-200.

Mod. PWT-400
Marca TONTARRA

Emesso il:	1999-05-10
Data aggiornamento:	2019-11-25
Sostituisce:	2018-11-07
Data scadenza:	2022-03-13

DocuSign

IMQ

CERTIFICATO CE

Certificato n. 187/MDD

Allegato

Elettrobisturi

Serie: TopTom Modd. TopTom SU 50; TopTom SU 100; TopTom SU 140; TopTom SU 140/D.

Serie: AMNOTOM Modd. AMNOTOM 160 BASE; AMNOTOM 400 COMPACT; AMNOTOM 400 PREMIUM; AMNOTOM 400 PREMIUM A.
Marca AMNOTEC

Carrelli non elettrificati per apparecchi per elettrochirurgia, aspiratori di fumi elettrochirurgici e aspiratori medicali

Modd. H10; H10/AB; H23/SE; H25; H26

Emesso il:	1999-05-10
Data aggiornamento:	2019-11-25
Sostituisce:	2018-11-07
Data scadenza:	2022-03-13

DocuSign

IMQ

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-16-372

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

CeramOptec GmbH

Siemensstrasse 44, 53121 Bonn, Germany
Facility: Brühler Strasse 30 53119 Bonn, Germany

Products: The products defined at the enclosure which is the part of this certificate and contains two pages.

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.4508.04
Date of first issue:	14 March 2016
Date of last issue:	13 March 2019
Revision Number:	02
Expiry Date:	12 March 2024

13 March 2019, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex II Section 3
Certificate Number: 1984-MDD-16-372, Revision Number: 02

Concerned medical devices;

Product: Diode Lasers
Types:
- Type Ceralas E
- Type Ceralas HPD
- Type Leonardo
- Type Leonardo HPD
- Type Leonardo Mini

Product: Probes for Lasers
Types:
- Type Bare Fiber, single-use, sterile
- Type Bare Fiber, reusable
- Type Endoprobe, single-use, sterile
- Type Gas Liquid Cooled, single-use, sterile
- Type Side Fiber, single-use, sterile
- Type PLDD Bare Fiber, single-use, sterile
- Type Cylindrical diffuser, single-use, sterile
- Type ELVeS Fiber, single-use, sterile
- Type Twister, single-use, sterile
- Type ELVeS Radial, single-use, sterile
- Type Bare fiber for Ho:YAG Laser, single-use, sterile
- Type Bare fiber for Ho:YAG Laser, reusable

13 March 2019, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex II Section 3
Certificate Number: 1984-MDD-16-372, Revision Number: 02

Concerned medical devices;

Product: Handpieces
Type: Type Derma Handpiece; reusable

Product: Introducer for Probes
Type: Type ELVeS Plus Catheter, sterile

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

13 March 2019, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

kiwa

Ceram●ptec

CeramOptec GmbH

Siemensstrasse 44 53121 Bonn Germany
Facility: Brühler Strasse 30 53119 Bonn Germany

with a scope of

Design, production, distribution and service of optical preforms, optical fibers and fiber optic delivery systems

Has established a quality management system in accordance with international standard.

" Following elements of the standard are excluded "

" None "

ISO 9001:2015

Certificate No	: M 10351
Initial Certification Date	: 14 March 2016
Certification Date	: 28 February 2019
Expiration Date	: 27 February 2022

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.

Please contact above numbers for detailed information.

Last Modified: 28 February 2019 - R 02

TÜRKAK
Quality Management System
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-CFC6-6520

CERTIFICATE

kiwa

Ceramoptec

CeramOptec GmbH

Siemensstrasse 44 53121 Bonn Germany
Facility: Brühler Strasse 30 53119 Bonn Germany

with a scope of

Design and development, manufacture, installation, distribution and service of fiber optic delivery systems and laser systems with accessories

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.5.9.2.2"

EN ISO 13485:2016

Certificate No	: M 10352
Initial Certification Date	: 14 March 2016
Certification Date	: 28 February 2019
Expiration Date	: 27 February 2022

General Manager

Kiwa Certification Services Inc.
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Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK
Medical Device O.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS
TÜRKAK BDS NO
YS-9247-79FB

Last Modified: 28 February 2019 - R 02