ECO.next & ECO.LUX

ISTRUZIONI PER L'USO
OPERATING INSTRUCTIONS
MODE D'EMPLOI
MANUAL DE INSTRUCCIONES

La casa costruttrice declina ogni responsabilità per le possibili inesattezze contenute nel presente manuale, imputabili ad errori di trascrizione e si riserva il diritto di apportare ai propri prodotti quelle modifiche che ritenesse necessarie o utili, senza pregiudicarne le caratteristiche essenziali.

Da conservare per futuri riferimenti.

The manufacturer declines all and any responsibility for possible inexactitudes due to typing errors contained in this manual and reserves the right to modify his products without changing their main characteristics, if he considers such modifications necessary or useful.

To be preserved for future consultation.

Le fabricant décline toute responsabilité pour les possibles inexactitudes contenues dans ce manuel, imputables à des erreurs de transcription ou traduction et se réserve le droit de modifier ses produits, sans modifier les caractéristiques essentielles, s'il le considère nécessaire ou utile.

À conserver pour l'éventuelle consultation future.

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Conserven este manual para futuras consultas.

Tutti i componenti in poliuretano prodotti da Tecnodent sono:

All polyurethane parts produced by Tecnodent are:

Tous les composants en polyuréthane produits par Tecnodent sont :

Todos los componentes de poliuretano producidos por Tecnodent son:

HCFC / Free

POLTRONA TIPO
CHAIR TYPE
FAUTEUIL TYPE
SILLON MODELO

ECO.next
ECO.LUX

ISTRUZIONI PER L'USO

OPERATING INSTRUCTIONS

MODE D'EMPLOI

MANUAL DE INSTRUCCIONES

TECNODENT
ERGONOMIC INNOVATION

INDEX

1. INTRODUCTION

1.1. DEFINITIONS.

This manual adopts the following graphic and linguistic conventions.

NOTE.

Contains important information, which should be highlighted with respect to the text.

CAUTION.

Before conducting certain procedures, this message may be displayed. If not observed, it could cause damage to the equipment.

WARNING.

Before conducting certain procedures, this message may be displayed. If not observed, it could cause damage to the operator and the equipment.

Double function control(s).

Foot operated switches which control the multiple chair functions, depending on how they are activated. For example, continuous activation: manual chair movement; short activation (tap): automatic movement of a pre-programmed working position.

Synchronized movement.

Simultaneous and interdependent positioning of the chair parts, which may be activated in an automatic or manual setting (e.g., raising the chair and simultaneously leaning the backrest).

Compensated movement.

Position variation of two chair parts acted by a motion system which takes into consideration ergonomic needs (e.g., backrest leaning movement).

PCB.

Electronic card (printed circuit board).

CN.

Electric connector.

PWR.

Power supply.

LED.

Light-emitting diode.

1.2. GENERAL WARNING.

Upon user request, Tecnodent agrees to provide circuit diagrams, list of component parts, calibration instructions or other information available, which will assist the user's technical personnel to conduct repairs of those parts of the chair which are considered repairable by the manufacturer.

WARNING.

The manufacturer will accept responsibility for the safety, reliability and performance of the equipment on the following conditions:

- **The installation operations, modifications or repairs have been performed by authorised personnel;**
- **The electrical system of the installation site conforms to the legal regulations and standards;**
- **The equipment is used in accordance with the operating instructions.**

NOTE.

Please note that in accordance with Art. 14 of EEC Directive 85/374 "Responsibility for damages arising from defective products" implemented in Italy by Decreto del Presidente della Repubblica on May 24, 1988, n. 224: "Right to compensation shall cease at the expiration of ten years from the day the manufacturer or the importer within the EU Nations has first marketed the product, which has caused the claimed damage".

1.3. DOCUMENTATION PURPOSE.

This manual shows the ECO.next and ECO.LUX chairs and contains information regarding their correct use, functions, performances, maintenance, troubleshooting and corresponding solutions.
This manual is intended for the final user, the professional that uses the equipment to perform his job.

1.4. DOCUMENT KEEPING.

This manual is part of the equipment and must be conserved until its disposal.
It should be stored in a protected location, but near the device, for prompt usage if necessary; if this documentation is lost, the user should request a replacement copy.

1.5. LIMITATION OF RESPONSIBILITY.

The Manufacturer must be relieved of any responsibility in the following cases:

- Improper use or usage by untrained personnel for professional use;
- Use contrary to the applicable standards;
- Improper installation, if it is not specifically included in the supply contract;
- Power supply failure or defects;
- Lack of maintenance or servicing;
- Unauthorised modification or interventions;
- Use of non-original spare parts, or not model-specific;
- Failure to comply with the instructions (even partially);
- Exceptional events.

1.6. TRANSPORT AND STORAGE.

The equipment, if contained in its original packaging, may be exposed for a period of no more than 5 weeks to environmental conditions within the following ranges:

	Min	Max
Temperature	-40° C	+70° C
Relative humidity (condensation included)	10%	95%
Atmospheric pressure	500 hPa (mbar)	1060 hPa (mbar)

1.7. PACKING DISPOSAL.

All materials used for packaging are recyclable and respect the environment:

- Wooden pallet with fumigation treatment;
- Cardboard box;
- Polythene film or bubblewrap.

Please deliver the packing to an authorized landfill, for the recovery of these materials.

1.8. END-OF-LIFE EQUIPMENT DISPOSAL INFORMATION.

According to the article 13 of D.lgs. no. 151, dated July 25th, 2005, "Implementation of the Directives 2002/95/EEC, 2002/96/EEC and 2003/108/EEC, concerning the reduction of hazardous substances in electric and electronic equipment, as well as waste disposal", and subsequent modifications such as D.lgs. no. 49, dated March 14, 2014, "Implementation of the Directive 2012/19/EEC concerning waste of electric and electronic equipment", Tecnodent states as follows.

- This symbol, placed in the identification label, indicates that the product at the end of its useful life must be disposed separately from other waste.
- The separate collection of end-of-life equipment is organized and managed by the manufacturer. The owner who wishes to dispose this equipment should contact the manufacturer or one of its representatives to allow separate collection of this end-of-life equipment.
- The correct separate collection for recycling, processing and environmentally friendly disposal helps avoiding potential adverse effects on human health, and promotes reuse and recycling of the equipment materials.
- Illegal disposal of the product by the owner will lead to penalties, as determined by the laws in force.
- If the product is placed out of use at the end of its working life, it is necessary to definitely put it out of service, by disconnecting the plug from the socket and cutting the power supply cable.

2. EQUIPMENT DESCRIPTION

2.1. INTENDED USE.

The product described by this manual is a dental patient chair.
The equipment is designed for lifting and holding the patient in a proper working position during dental diagnosis or therapy.
The chair can be also suitable for more generic use, in relation to the basic positioning of the patient. In case of any doubt, contact the manufacturer for further details.
It can be used by specialists in private clinics, hospital structures, specialized wards.
The apparatus requires the use of a compliant electrical installation, as specified in the section "installation". It is not advised for usage in close proximity with devices which monitor patient vital functions.
Essential performance of the device is holding the patient in any normal use situation, in fault condition too.

WARNING.

The equipment was developed and manufactured only for dental use. It can be also utilised for different generic fields. For more information, ask the manufacturer.
It is furthermore prohibited to perform any modification of the equipment or its parts, without explicit written authorization of the manufacturer.

2.2. GENERAL FEATURES.

2.2.1. Basic version.

A patient chair model ECO.next or ECO.LUX presents the following functions:

- Completely electromechanical seat lifting/lowering and backrest tilting movements;
- Compensated backrest tilting, up to the horizontal position;
- Anatomical narrow backrest;
- ELLE 2 MOBILE type headrest;
- Complete symmetry, for right-handed and/or left-handed professionals;
- Safety STOPS on the backrest, on the base and on the lifting arm;
- Return to patient exit ("zero") position automatic programme;
- Rinse position automatic program;
- Low voltage controls (5 V).

2.2.2. Accessories.

The chairs can also be equipped with different accessories, depending on the working needs of the professional, as well as the comfort needs of the patient to be treated. In detail, the following options are available:

- "UNI tappezzato" type headrest;
- Anatomical large backrest;
- Magnetic pillow model C95;
- Magnetic pillow model C2002;
- Right or left armrest(s);
- Device for rotation around the vertical axis, installed under the seat;
- Device for programming three different working positions;
- Trendelenburg movement;
- Foot control, on the base;
- Mobile foot control;
- Infra-red remote control.

The operation and the performance of these accessories are described in chapter 7.

2.3. WARRANTY.

NOTE.

Upholstery damage caused by contact with clothes or clothing accessories (ex: belts) having metal, sharp, pointed or similar parts will not be replaced under warranty.

CAUTION.

The use of disinfectants or detergents with a strong alcoholic content on the apparatus damages the surface of the product, especially the upholsteries.

2.4. IDENTIFICATION AND LABELLING.

The identification label is placed in the base of the chair under the seat. It indicates the chair model, serial number and other information. Figure 1 highlights the label position and a facsimile.

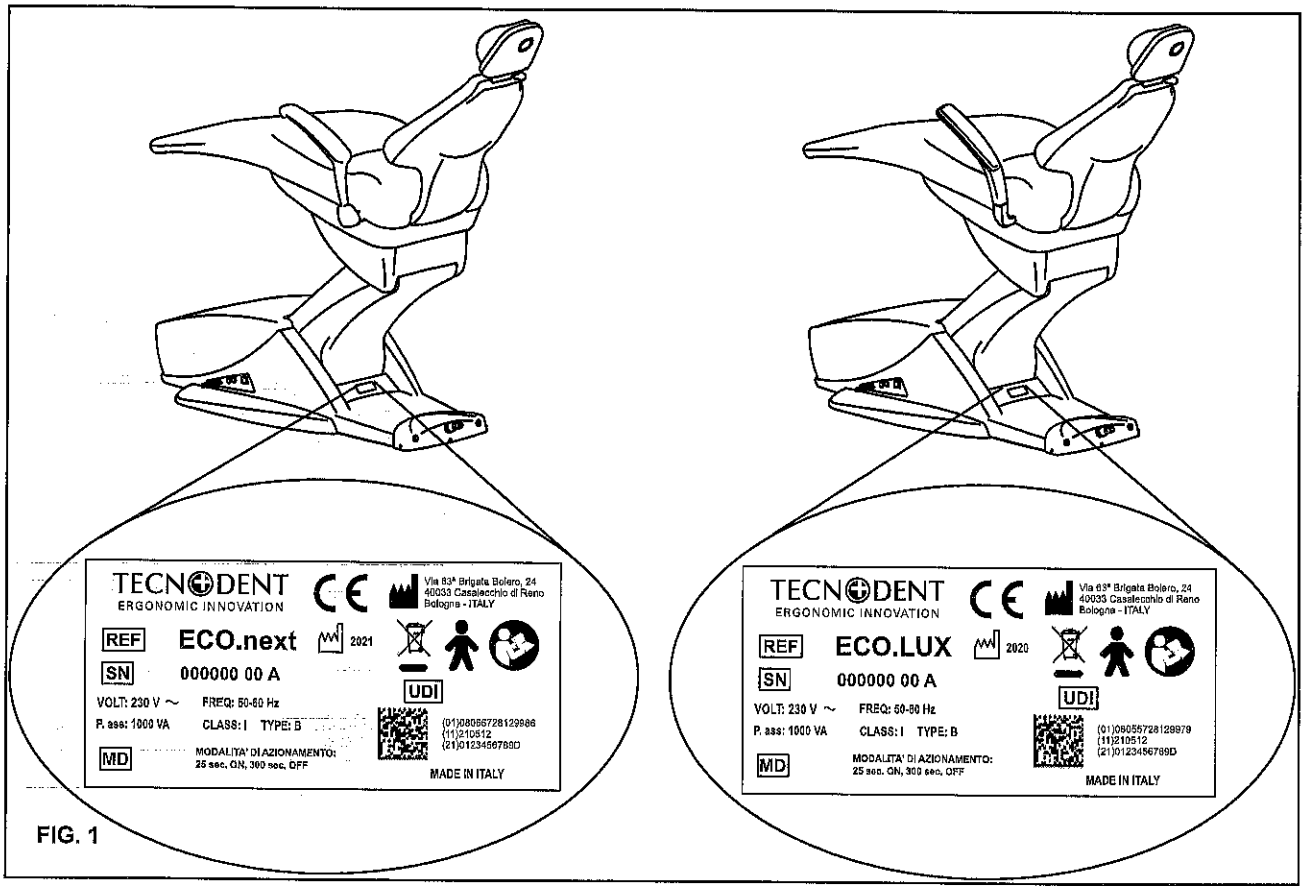


FIG. 1

	Manufacturer.		Manufacturing date.
REF	Model. It identifies unambiguously the device of the product family.	SN	Serial number of the device.
MD	Medical device.	UDI	UDI code. UDI coding may not be shown on the label.
	Read the operating instruction carefully.		Contains type B applied parts.
CE	CE marking.		Dispose of the product in compliance with the procedures provided for electric and electronic equipment.

2.5. TECHNICAL SPECIFICATIONS.

2.5.1. Sector-specific standard compliance.

The patient chairs, for dental or generic use, model ECO.next and ECO.LUX comply with the Regulation (EU) 2017/745 (MDR), concerning medical devices.
Specifically, design and manufacture of the equipment comply with the following international standards:

EN 60601-1:2006 / A11 A1 EN 60601-1:2015 EN 80601-2-60:2015

2.5.2. Technical data.

ELECTRICAL SPECS.

Voltage	V	230 ± 10%	110 ± 10%
Frequency	Hz	50 – 60	
Input power	VA	1000	1000
Main fuses		2 x T 6,3A; 250V	2 x T 10A; 110V
Operating mode		Intermittent loading 25s ON 300s OFF	Intermittent loading 20s ON 300s OFF
Insulation class		I	
Applied part type		B	
Controls voltage	V	5	
Medical device risk class		I	

PERFORMANCES.

Chair type		Without rotation	With rotation
Minimum space required for installation	m	3 x 2	3 x 3
Max. height	mm	780	795
Min. height	mm	380	395
Rotation angle	deg	-	±30°
Trendelenburg (if present)	deg	15° (±2°)	
Width	mm	660	
Length (with completely elongated headrest)	mm	2050	
Packing dimensions	mm	1430x700x1105 (h)	
Gross weight	Kg	170	
Net weight	Kg	140	
Maximum lifting capability (patient + unit)	Kg	135 + 75	
External controls interface		Yes	

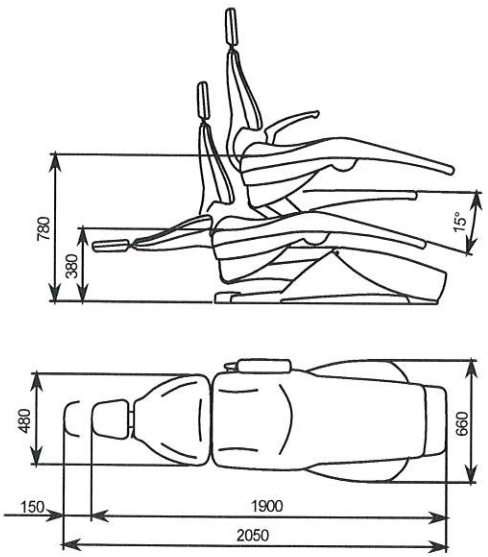
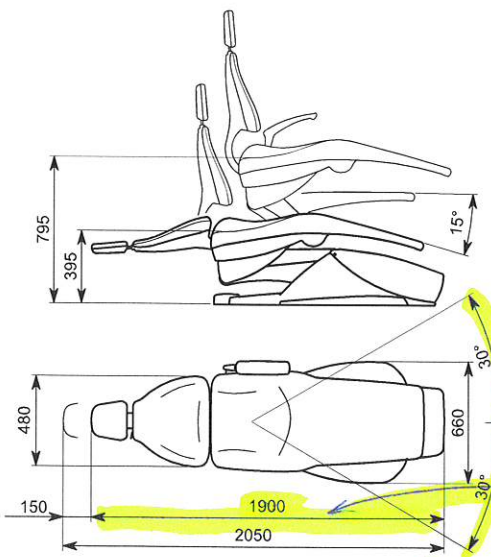


FIG. 2 Chair without rotation



Chair with rotation

2.5.3. Electromagnetic compatibility.

ECO.next and ECO.LUX chairs do not cause influences of an electromagnetic nature or other type with other equipment, nor are them susceptible to influences from other devices, and are compliant with the requirements of the harmonized standard EN 60601-1-2.

The following tables provide details on the electromagnetic environment in which the product can be used.

Emission aspects.

Emission test	Conformity	Electromagnetic environment – guide
RF Emissions Cispr 11	Group 1	The product uses RF energy for its internal function only. Therefore, its RF emissions are extremely low and not likely to cause interference with nearby electronic devices.
RF Emissions Cispr 11	Class B	It is possible to use the equipment in all buildings, including domestic use buildings, and those directly connected to a public power supply network with a low voltage supplying buildings for domestic use, taking installation steps, and guaranteeing an increased installation distance for potentially sensitive devices.
Harmonic emissions IEC 61000-3-2	Class A Conformity	It is possible to use the equipment in all buildings, including domestic buildings, and those directly connected to a public power supply network with a low voltage supplying buildings for domestic use.
Emission fluctuations voltage/flicker IEC61000-3-3	Conformity	

Immunity aspects.

ECO.next and ECO.LUX chairs are intended for use in an electromagnetic environment under specification. The customer or user should ensure that it is used correctly in such an environment.

Immunity test	Test level EN 60601-1-2	Conformity level	Electromagnetic environment – guide
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Burst / Fast transient EN 61000-4-4	±2kV power supply lines	±2kV power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5% UT (>95% dip UT) for 0,5 cycles 40% UT (60% dip UT) for 5 cycles 70% UT (30% dip UT) for 25 cycles < 5% UT (>95% dip UT) for 5 seconds	< 5% UT (>95% dip UT) for 0,5 cycles 40% UT (60% dip UT) for 5 cycles 70% UT (30% dip UT) for 25 cycles < 5% UT (>95% dip UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field EN 61000-4-8	3 A/m	3 A/m	Magnetic power frequency fields should be that of a typical commercial or hospital environment.

Immunity aspects at RF.

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an electromagnetic environment.

Immunity test	Test level EN 60601-1-2	Compliance level	Electromagnetic environment – guide
RF conducted EN 61000-4-6	3 Veff from 150kHz to 80MHz	3 Veff from 150kHz to 80MHz	Portable and mobile RF communication equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2 \cdot \sqrt{P}$ from 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2,3 \cdot \sqrt{P}$ from 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
RF radiated EN 61000-4-3	3 Veff from 80MHz to 2,5GHz	3 Veff from 80MHz to 2,5GHz	
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:			

Recommended separation distances between portable and mobile RF communication equipment and the device.

ECO.next and ECO.LUX chairs are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of the transmitter (m)		
	From 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$	From 80MHz to 800MHz $d = 1,2 \cdot \sqrt{P}$	From 800MHz to 2GHz $d = 2,3 \cdot \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer. Notes. (1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

3. INSTALLATION

3.1. UNPACKING.

To remove the cardboard box, it is necessary to cut the straps and to unscrew the screws located in the lower part of the box.

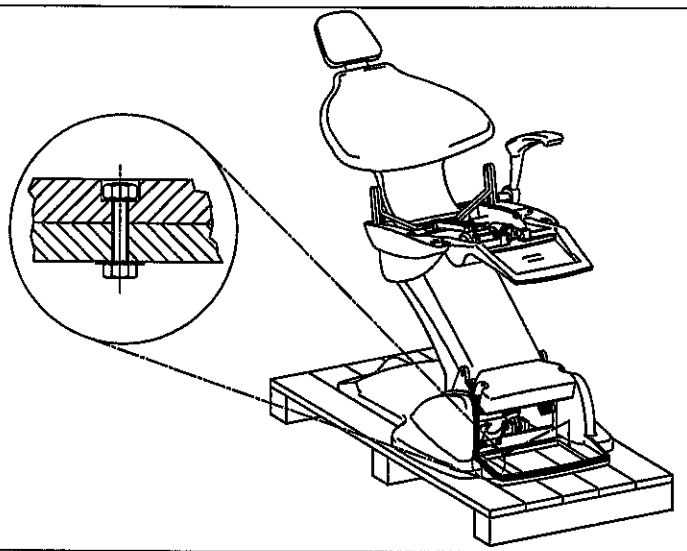


FIG. 3

3.2. SUPPLY STATUS.

The following elements must be contained inside the packaging:

- An ECO.next or ECO.LUX chair;
- An operating instruction manual;
- A bottle of fabric cleaner;
- Two transportation handles.

In case of mistake or missing parts, contact the dealer.

3.3. HANDLING.

To remove the chair from the wooden pallet, unscrew the two screws that fix the chair base to the pallet (see figure 3).
To move the chair from the wooden pallet, employ two people.
To move the chair, hold it by the handles.
After positioning the chair, remove the handles as follows (see figure 4):

- Unscrew the hexagonal screws 1 and 2;
- Remove the "U" shaped handle, near the lower body;
- Unscrew the hexagonal screws 3 and 4;
- Remove the "L" shaped handle, near the upper body.

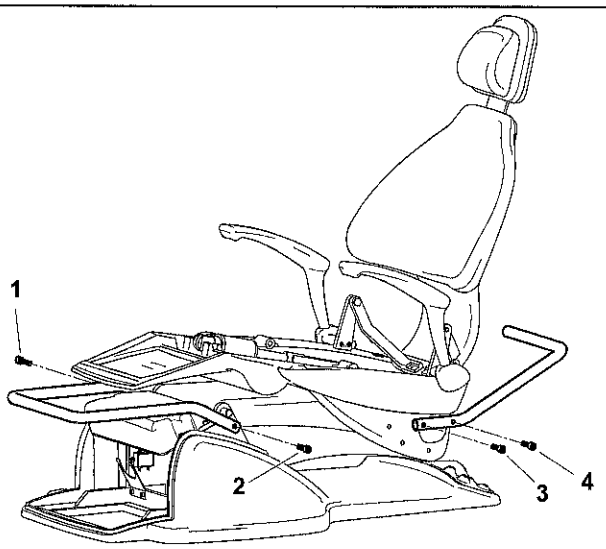


FIG. 4

3.4. INSTALLATION.

3.4.1. Typical installation.

Proceed as follows.

1. Be sure that the installation site conforms to local regulatory technical requirements for medical studios or outpatient clinics.
2. Be sure that the electrical system of the cabinet has a safe earthing and a residual-current device system.
3. Be sure that the main supply of the electrical wiring of the cabinet corresponds to the one of the identification label.
4. Check that the fuses, located at the front side of the chair near to the base, are correctly fixed, because during transport they could have become loose.
5. Insert the plug into the socket.
6. Activate the main switch to turn on the chair. Now the chair is ready for use. In case of non-operation of the chair, refer to section 6 about troubleshooting.
7. If needed, drive the chair to a comfortable height and assemble, if provided, the unit bracket and the unit itself, following the instructions of the manufacturer.

NOTE.

Equipment must not be used in potentially explosive environment, or in rooms not protected against weather conditions. Not suitable for use in altered atmospheres.

3.4.2. Position choice and stability.

To ensure a good chair installation, please verify the stability and flatness of the floor in the location where the product will be installed: if necessary, a damaged or unstable floor should be repaired.

The chair is designed to remain stable without floor fixing. However, according to the unit characteristics (dimensions, space required, weight) it could be necessary to fix the chair to the floor, using the appropriate holes in the base (figure 5, locations A and B).

For further information, ask the installer.

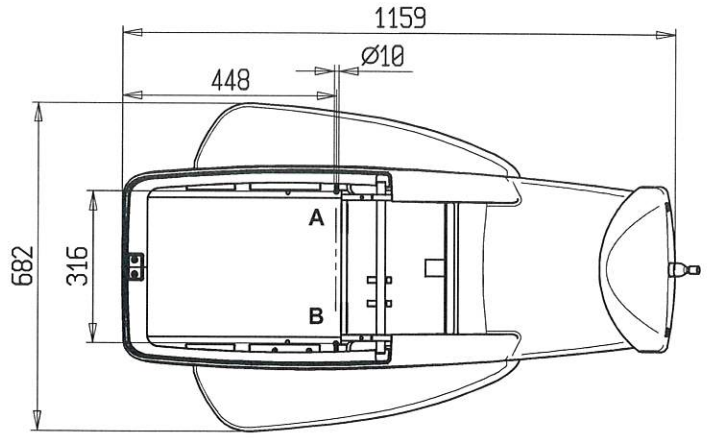


FIG. 5

WARNING.

Tecnodent declines all and any responsibility for damage caused by the non-compliance with the above instructions.

4. USING THE PRODUCT

The advanced technology applied to the production of this apparatus has allowed the design of a patient chair with multiple functions and performances, all of them easily usable: all regulations and functions of the chair are coordinated, processed and stored in a "data bank", by a microprocessor inside the chair. The patient chairs ECO.next and ECO.LUX are designed to be easily controlled by foot controls, allowing the professional's hands to be completely free to operate in the patient's mouth.

WARNING.

Before using the information contained in this section, make sure that the chair is correctly installed, by the service technician.

CAUTION.

Use in a clean place (specialized surgery, clinic) and avoid accidental spilling or falling of liquid substances on the product.

CAUTION.

In case of a product malfunction that is not described in this documentation, put equipment out of service (shut it down, unplug main supply, mark the equipment as "out of order" or similar) and call the technical service.

4.1. TYPICAL USE.

To use the product, the operator must be near the chair, typically on the back of the chair or sideways, while acting on the controls. Care should be taken throughout the operation of the product, as the presence of automatic movements could cause hazardous situations, even if moderate level ones.
The chair is provided with several emergency stop systems, e.g., in case of presence of obstacles during the movements, or if the operator checks any unsuitable situation.

WARNING.

Do not overload the leg rest, e.g., by sitting on the front part of the upholstery.

4.2. CONTROLS.

The controls are shown in figure 6.

NOTE.

Depending on the configuration chosen, the chair may not be provided with foot controls as described below, because the chair is also designed to be controlled by other devices (e.g., a dental unit).
Please refer to section 7 for more information on optional controls

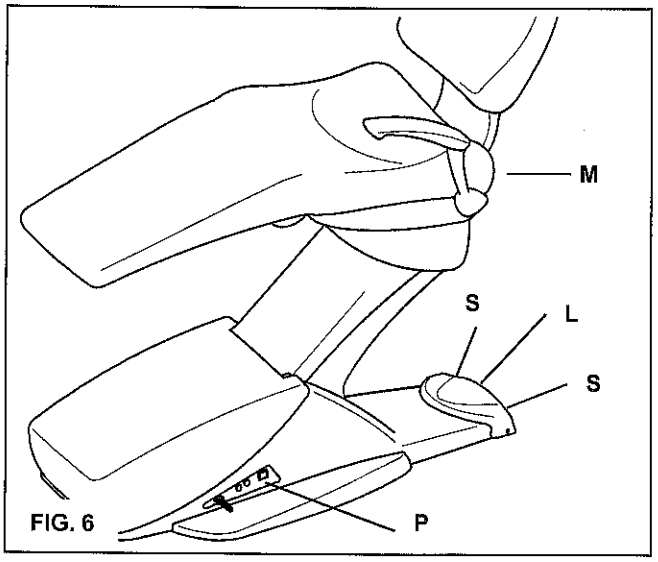


FIG. 6

CHAIR WITHOUT PROGRAMMES.

P Main switch (Power on/off).

L Foot control, placed on the base. It controls raising, lowering and backrest tilt manual movements of the chair and the automatic return to patient exit ("zero") position.

S Control the automatic movement of rinse position, in order to allow the patient's mouth wash and the return to the last working position.

CHAIR WITH PROGRAMMES.

P Main switch (Power on/off).

L Double function foot control, placed on the base. It controls the raising, lowering and backrest tilt manual movements of the chair, as well as the 3 programmable working positions and the automatic reset to patient exit ("zero") position.

S Control the automatic movement of rinse position, in order to allow the patient's mouth wash and the return to the last working position.

M Stores the programmed working positions.

4.3. CHAIR OPERATIONS.

4.3.1. Chair without programmes.

Connect the plug in the socket and switch on the chair with the main switch. The chair is now ready to be used.

"L" FOOT CONTROL OPERATION

The rear base foot controls are provided with a joystick and two buttons (see figure 7).
To control the main movements, move the joystick with the foot in the allowed directions.

- While keeping the joystick downward, the chair lowers.
- While keeping the joystick upward, the chair lifts.
- While keeping the joystick to the right of the chair, the backrest moves to the vertical position.
- While keeping the joystick to the left of the chair, the backrest moves to the supine position.
- While tapping the joystick downward, the chair moves automatically to the patient exit position.

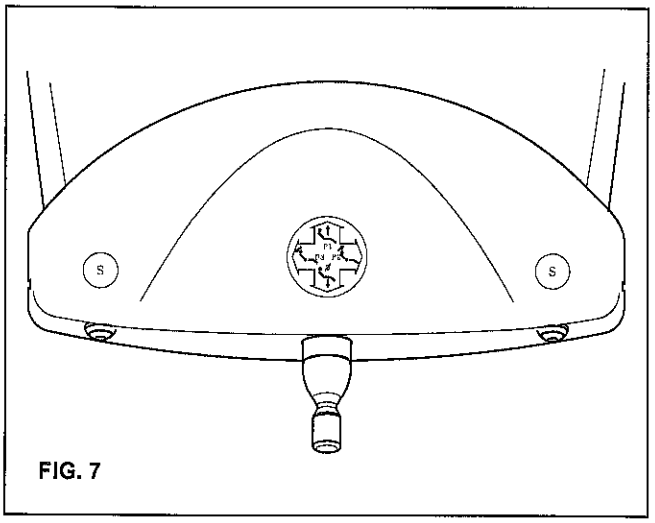


FIG. 7

"S" BUTTON OPERATION

While pushing "S" the rinse position function is activated; the chair backrest moves up to vertical position to allow the mouthwash.
While pushing "S" again the chair backrest moves back to its last position.

NOTE.

Any switch, if pushed during an automatic movement or during the automatic reset to "zero" position movement, works like a safety STOP.

4.3.2. Chair with programmes.

Connect the plug in the socket and switch on the chair with the main switch. The chair will emit a double sound signal ("BEEP – BEEP"), which indicates that the chair is ready for use.

"L" FOOT CONTROL OPERATION

- While keeping the joystick downward, the chair lowers.
- While keeping the joystick upward, the chair lifts.
- While keeping the joystick to the right of the chair, the backrest moves to the vertical position.
- While keeping the joystick to the left of the chair, the backrest moves to the supine position.
- While tapping the joystick upward, left or right, the chair moves automatically to the programmed working positions.
- While tapping the joystick downward, the chair moves automatically to the patient exit position.

NOTE.

To distinguish between "keep pressed" and "tap", the chair controller needs a delay of approximately 0.5 seconds.

"S" BUTTON OPERATION

While pushing "S" the rinse position function is activated; the chair backrest moves up to vertical position to allow the mouthwash.
While pushing "S" again the chair backrest moves back to its last position.

NOTE.

Any switch, if pushed during an automatic movement or during the automatic reset to "zero" position movement, works like a safety STOP.

PROGRAMMING PROCEDURE

This function is only available on chairs equipped with such feature.

1. Set the chair to the patient exit position by tapping the joystick downward.
2. Configure the chair to the desired position by activating the corresponding foot controls (see paragraph 4.3).
3. While keeping the M button pressed, tap the joystick upward ("P1"), right ("P2") or left ("P3"), according to the selected program number.

An acoustic signal ("BEEP") indicates that the work position has been memorised.
Every time that the joystick is tapped upward, right or left, the chair will automatically configure to the selected pre-programmed working position.

NOTE.

To avoid losing the programmed position, it is recommended to regularly set the chair to its "zero" position, by using the "0" function at any patient change.

5. MAINTENANCE

5.1. GENERAL INFORMATION.

ECO.next and ECO.LUX chairs were conceived to not require any servicing during their working life. Consequently, it is not required to perform any adjustment of the equipment. If the chair will not be used for some time, it is recommended to cover it with a cloth, to turn off the main switch, and to disconnect the plug from the socket.
If you use the ECO.next and ECO.LUX chairs according to the technical specifications and operating instructions in this manual, their useful life has been calculated to be 10 years, based on laboratory simulations.
After that time, it is necessary to have the chair serviced by qualified personnel, especially the electronic parts and those subject to wear.

WARNING.

Any technical adjustment, as well as any repair of the equipment not specifically listed in this chapter, must be carried out by qualified technicians.

5.2. CLEANING.

For a better and longer life of the equipment, it is necessary to perform an accurate, methodical and periodical general cleaning of the chair. It is recommended to proceed as follows.

CAUTION.

The use of disinfectants or detergents with a strong alcoholic content on the apparatus damages the surface of the product, especially the upholsteries.
It is recommended to avoid the use of any dissolvent, strong detergent or abrasive agent, even to remove "difficult" stains.

5.2.1. Upholsteries.

The fabric that covers the chair upholstery has to be cleaned using the liquid contained in the bottle kit supplied with the chair, using a soft cloth to avoid any surface scratching and to guarantee a better elasticity and smoothness of the surface.

NOTE.

Once the liquid detergent has been consumed, please contact the nearest assistance centre for new product.

5.2.2. Plastic or metal parts.

The polyurethane parts, as well as the metal parts (painted and not) have to be cleaned with a soft cloth dipped in water and soap.

5.3. MAIN FUSES REPLACEMENT.

ECO.next and ECO.LUX chairs are protected against electrical power overrating by two fuses, placed as shown in figure 8. To replace them, proceed as follows:

1. Turn off the chair's main switch;
2. Disconnect the plug from the socket;
3. Unscrew the fuse holder cap, by using a crosshead screwdriver of medium size;
4. Replace the damaged fuses;
5. To re-install the fuses, follow the inverse sequence of the above steps.

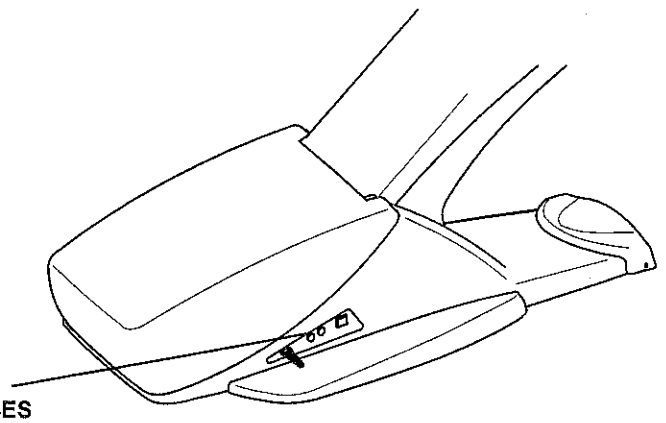


FIG. 8 FUSES

Tecnodent opera una politica di continuo sviluppo dei prodotti.
In questa ottica, Tecnodent si riserva il diritto di variare in qualsiasi momento e senza previa comunicazione le caratteristiche tecniche ed estetiche dei prodotti, qui riportate, che non risultano pertanto vincolanti o impegnative.

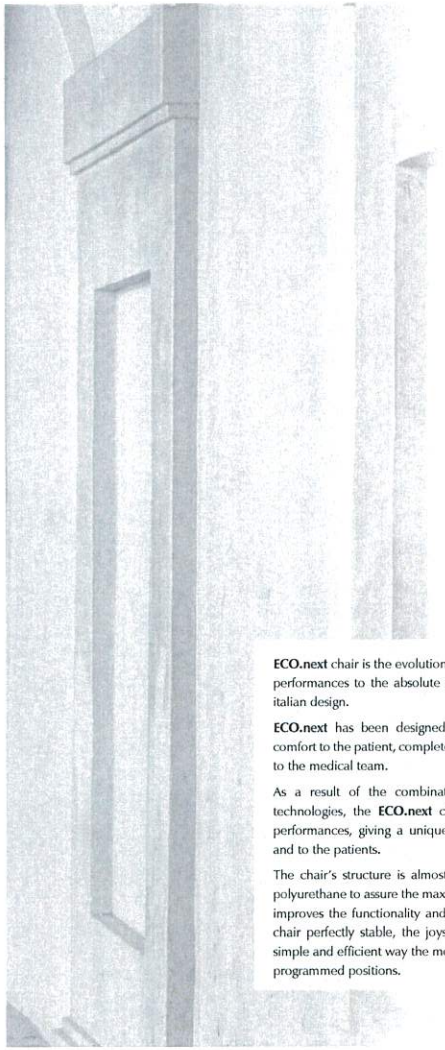
Tecnodent pursues a policy of continuous product development.
Therefore, Tecnodent reserves all rights to change the technical and aesthetical characteristics of the product at any time.

Tecnodent suit une philosophie de recherche continue sur les produits.
Tecnodent se réserve donc le droit de changer à tout moment et sans préavis les caractéristiques techniques et esthétiques des produits présents dans ce manuel qui n'engagent cependant en rien ou ne sont obligatoires.

Tecnodent sigue una política de constante desarrollo de sus productos.
Tecnodent se reserva el derecho de modificar en cualquier momento y sin necesidad de aviso previo las características técnicas y estéticas de los productos que aparecen en este manual por lo que no deben considerarse vinculantes.

kiwa certified
SISTEMA DI GESTIONE CERTIFICATO
UNI EN ISO 9001:2015
UNI EN ISO 13485:2016

TECNODENT
ERGONOMIC INNOVATION
Tecnodent S.r.l.
Via 63° Brigata Bolero – 24 – 40033 – Casalecchio di Reno (BO) – Italy
Tel. +39 051 613 11 43 – Fax +39 051 575 402 – P.IVA 02807791203
http://www.tecnodent.com – e-mail: info@tecnodent.com



ECO.next chair is the evolution of a great classic that mixes high performances to the absolute pleasure of refined and timeless italian design.

ECO.next has been designed to offer maximum anatomical comfort to the patient, complete ergonomics and perfect hygiene to the medical team.

As a result of the combination of different materials and technologies, the **ECO.next** chair matches comfort and high performances, giving a unique experience to the professional and to the patients.

The chair's structure is almost completely covered in integral polyurethane to assure the maximum strength, the compact base improves the functionality and the two lateral wings make the chair perfectly stable, the joystick pedal controls directly in a simple and efficient way the movements and allows to reach the programmed positions.

STANDARD AND OPTIONAL CHARACTERISTICS

• Standard · Optional

		2009new	ECO19	ECO.next	Linda3	Sling
Headrests	ELLE FISSO	•			•	
	ELLE/ELLE2 MOBILE	·	•	•	·	·
	UNI/Light	·	·	·	·	•
Pillows	C95	·	·	·	·	·
	C2002	·	·	·	·	·
Backrest	Narrow	•	•	•		
	Large	·	·	·	•	•
	"T" shaped	·				
Armrest	Right armrest	·	·	·	·	·
	Left armrest	·	·	·	·	·
Pregrams	Return to "zero" program	•	•	•	•	•
	Rinse program	•	•	•	•	•
Unit connection	Double side drilled upper body	·	·	·	•	·
	Fixed central arm		·	·		
	Rotation	·	·	·	·	·
	Rotation with central arm	·	·	·		·
	Trendelenburg	·	·	·	•	·
Function	Knee-break legrest				•	
	Securities	•	•	•	•	•
	Small integrated utility box		·			
	Large integrated utility box	•		•		•
	Joystick			•	•	•
Control	Foot control on the base	•	•			
	Mobile foot control	·	·	·	·	
	Infrared remote control			·	·	·

HEADRESTS

Tecnodent manual Headrests are available in 4 different models: ELLE FISSO, ELLE/ELLE2 MOBILE, UNI and Light. Every headrest was made for meeting every operator's need.


ELLE/ELLE2

ELLE/ELLE2. ELLE/ELLE2 FISSO has only the movment along its vertical axis. ELLE/ELLE2 MOBILE is an anatomical headrest, characterized by movement of inclination of the upper part (double articulation) for a correct cervical support.


C95


C2002

Magnetic pillows. ELLE/ELLE2 type, both fix and mobile version, can be combined with magnetic pillow C95 or C2002. Either pillow can be applied directly on the backrest, for ensure a better comfort, independently of the patient's height.


UNI


Light

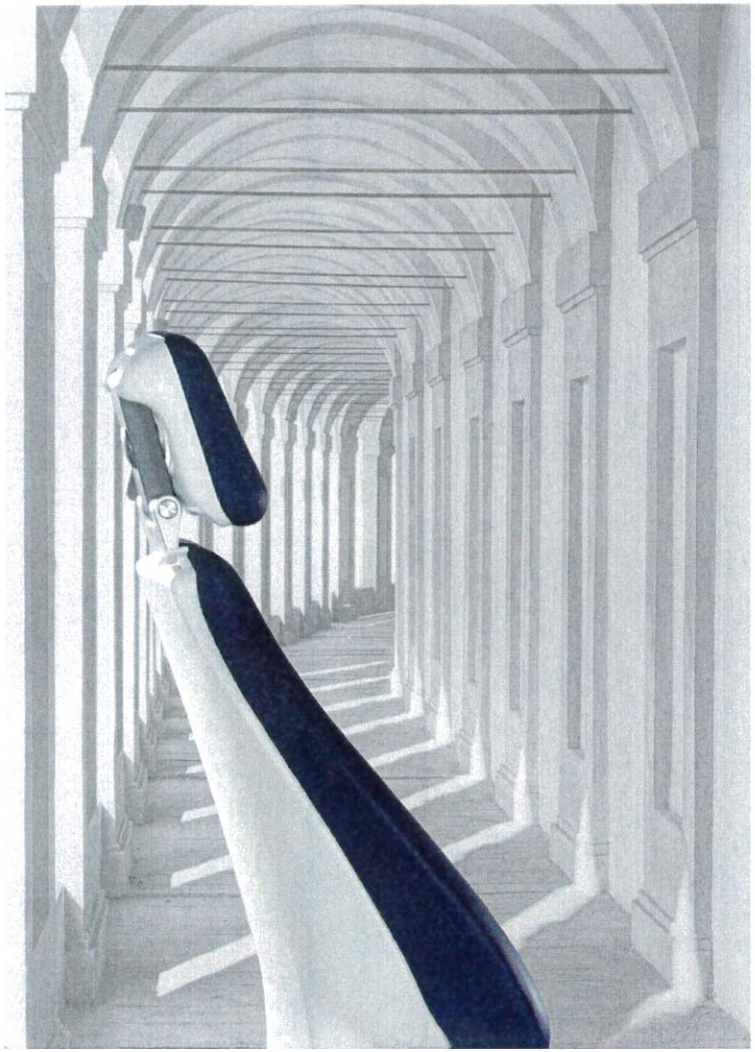
UNI and Light. The UNI and Light headrests are multi-articulated and allows positioning of the headrest along 3 axis.

TECNODENT
ERGONOMIC INNOVATION

Tecnodent S.r.l. Via 63° Brigata Bolero, 24 – 40033 Casalecchio di Reno (BO), Italy
Tel. +39 051 6131143 – Fax +39 051 575402 – info@tecnodent.com – www.tecnodent.com

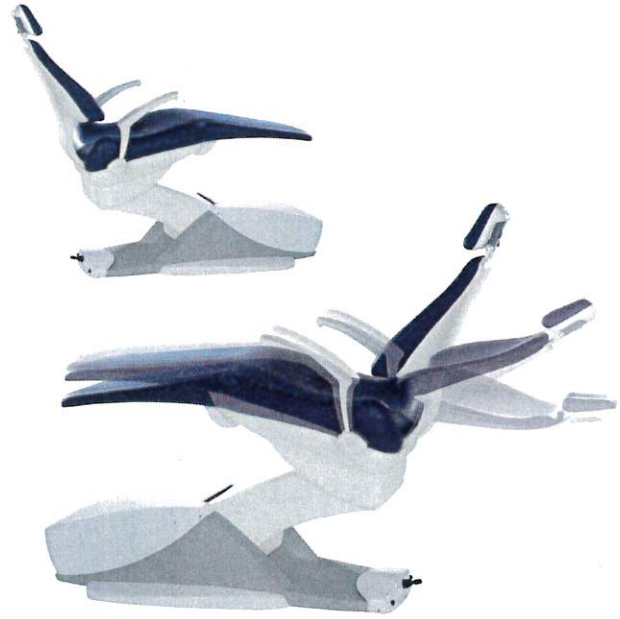
ECO.next

TECNODENT
ERGONOMIC INNOVATION



ECO.next

- Electromechanical lifting, lowering and tilting movements;
- Compensated backrest tilting, up to the horizontal position;
- Narrow and slim anatomical backrest for the maximum liberty of action of the professional;
- Multi-articulated anatomical headrest ELLE2 MOBILE for a patient's comfortable posture and for a perfect visuality during the treatment;
- Wrapping seamless upholstery in high quality leatherette fabric;
- Possible customization with different colors of polyurethane and leatherette fabric;
- Integrated utility box;
- Complete symmetry for right-handed or left-handed professional;
- Joystick control on the base for fast and efficient movements of the chair without using the hands, assuring a perfect hygiene;
- Security STOPS on the backrest, on the base and on the pantograph arm;
- Return to "zero" position automatic program;
- Rinse position automatic program;
- Possibility to program 3 different working position (OPTION);
- Possibility to equip the chair with one/two rotating armrests to improve the accessibility of the chair and to assure a natural support for the arms, allowing a relaxed position during the treatment (OPTION).



Narrow backrest
This backrest was studied to allow the doctor the closest approach to the patient during the treatment, also guaranteeing an excellent comfort to the patient.

Large anatomical backrest (OPTION)
Guarantees the maximum comfort, wrapping the patient's back in a pleasant relax.

Trendelenburg Movement (OPTION)
At 15°, with automatic compensation of the backrest for a correct blood flow during the treatment.

Rotation (OPTION)
Rotating device which allows the chair to rotate around the vertical axis by a lever under the seat.

Mobile foot control "Easy Touch" (OPTION)
Easy and functional foot control which provides different precise treatment positions and doctor's hands-free control.

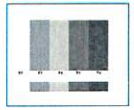
Right and/or left armrest (OPTION)
Rotating armrests help the patient to get on/off the chair.

Infrared remote control (OPTION)
Manual control of the movements and set to reach programmed positions.

Unit/lamp attachment (OPTION)
Drilled body for fastening dental unit/lamp.

Central arm (OPTION)
Unit fixing and rotating arm for ambidextrous functionality.

Polyurethane colors
Possibility to choose between 5 different colors.



TECHNICAL FEATURES

Maximum height	mm	Without rotation 780	With rotation 795
Minimum height	mm	Without rotation 380	With rotation 395
Backrest tilting angle	°	-15/+65	
Rotation angle	°	±30	
Width	mm	660	
Length (without headrest)	mm	1570	
Length (with headrest)	mm	2050	
Gross weight	Kg	170	
Net weight	Kg	140	
Maximum lifting capability (patient + unit)	Kg	135+75	
Classification		I	
Type		B	

TECNODENT
ERGONOMIC INNOVATION

DICHIARAZIONE CE DI CONFORMITÀ

EU declaration of conformity

Il fabbricante
The manufacturer

TECNODENT S.r.l.
Via 63a Brigata Bolero, 24
40033 Casalecchio di Reno (BO) – ITALY
SRN: **IT-MF-000027920**

dichiara sotto la propria totale responsabilità che il seguente prodotto
declares under its own exclusive responsibility that the following product

Modello *Product Name*	ECO.NEXT
Destinazione d'uso *Intended use*	Poltrona dentale. Poltrona ad uso generico per applicazioni correlate al semplice posizionamento del paziente *Dental patient chair; General purpose chair for simple patient positioning - related applications*

UDI di Base (*basic UDI*): **8055728120000PDENTALN4**

È conforme ai requisiti essenziali di sicurezza come da allegati I ed alle prescrizioni di MDR 2017/745
Complies to the essential safety requirements and prescriptions of Medical Devices Regulation 2017/745

CE

Classe del dispositivo medico *Medical device class*	I *(ref. MDR2017/745, All. VIII regola 13)* *(ref. MDR2017/745 Annex VIII rule 13)*
Procedura di certificazione *Certification procedure*	Allegato II + Allegato III *Annex II & Annex III*

L'azienda dichiara inoltre che i prodotti indicati nel presente dichiarazione di conformità sono:
- Conformi alla Direttiva 2011/65/UE (Restriction of Hazardous Substances), sulla restrizione dell'uso di sostanze pericolose nelle apparecchiature elettriche ed elettroniche, comprese le disposizioni della Direttiva Delegata (UE) 2015/863 emanata dalla Commissione Europea.

TECNODENT moreover hereby states, that the products mentioned in this Declaration of Conformity are compliant with Directive 2011/65/EU (Restriction of Hazardous Substances) concerning the restrictions on the use of hazardous substances in electrical and electronic equipment, including the provisions of Commission Delegated Directive (EU) 2015/863 issued by the European Parliament and the Council.

Casalecchio di Reno (BO)
14/09/2022

Il Consigliere Delegato

Massimiliano Tabacchi
(Member of the Board)

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UNI EN ISO 9001:2015
UNI CEI EN ISO 13485:2016

TECNODENT S.r.l. Società Unipersonale
Via 63a Brigata Bolero, 24
40033 CASALECCHIO DI RENO - BOLOGNA (ITALIA)
Tel. 39 - 051 61 31 143 - Telefax 39 - 051 57 54 02
Internet: www.tecnodent.com - E-mail: info@tecnodent.com

Capitale Sociale € 100.000 int. vers.
P. I.V.A. IT02807791203
Cod. Fisc. e Reg. Imp. di Bo N. 02807791203

TECNODENT
ERGONOMIC INNOVATION

TO WHOM IT MAY CONCERN

We, company TECNODENT Srl, located in Casalecchio di Reno (Bologna) Italy, Via 63a Brigata Bolero 24, as manufacturer of dental/ medical chairs and stools we hereby authorize our partner LIMETA Jsc. Graiciuno str. 4, LT-02241 Vilnius, Lithuania (Company code: 221906050 - VAT code: LT219060515) to supply and install our production range, provide after sale, warranty services, promote and train his employees on Tecnodent products in its territory of competence.

Best regards.

Casalecchio di Reno, March 21st 2022

TECNODENT Srl
Elisa Guidubaldi
General Sales Manager

kiwa certified
UNI EN ISO 9001:2015
UNI CEI EN ISO 13485:2016

TECNODENT S.r.l. Società Unipersonale
Via 63a Brigata Bolero, 24
40033 CASALECCHIO DI RENO - BOLOGNA (ITALIA)
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TECNODENT
ERGONOMIC INNOVATION

TO WHOM IT MAY CONCERN

We, company TECNODENT Srl, located in Casalecchio di Reno (Bologna) Italy, Via 63° Brigata Bolero 24, as manufacturer of dental / medical chairs and stools we hereby state that:
ECO NEXT patient chair footrest section is equipped with a transparent protective plastic cover that can be easily removed for cleaning purposes.

Best regards.

Casalecchio di Reno, January 9th 2023

TECNODENT SRL
Elisa Guidubaldi
General Sales Manager

kiwa certified
UNI EN ISO 9001:2015
UNI CEI EN ISO 13485:2016

TECNODENT S.r.l. Società Unipersonale
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Cod. Fisc. e Reg. Imp. di Bo N. 02807791203

STOMADENT®

CERTIFICATE

for authorized service technician:

A. Blokhin

According to attended training and successfully carried out examinations in STOMADENT training center we hereby certify the authorization to carry out service operations of under-mentioned products:

Dental Units:

STOMADENT IMPULS
STOMADENT GLANC
STOMADENT NEO

Dental Chair:

STOMADENT DC-70
STOMADENT NEO

For this purpose we are pleased to hand over this certificate

SLOVAKIA
STOMADENT
DIČO:SK2022302667
IČO:36722138
STOMADENT SK s.r.o., č.d. 300, 06601 Lackovce

STOMADENT SK s.r.o.
HUMENNÉ, January 18st, 2021

Valid to January 18st, 2026

STOMADENT®

CERTIFICATE

for authorized service technician:

Vidas Sileikis

According to attended training and successfully carried out examinations in STOMADENT training center we hereby certify the authorization to carry out service operations of under-mentioned products:

Dental Units:

STOMADENT IMPULS
STOMADENT GLANC
STOMADENT NEO

Dental Chair:

STOMADENT DC-70
STOMADENT NEO

For this purpose we are pleased to hand over this certificate

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DIČO:SK2022302667
IČO:36722138
STOMADENT SK s.r.o., č.d. 300, 066 01 Lackovce

STOMADENT SK s.r.o.
HUMENNÉ, January 18st, 2021

Valid to January 18st, 2026

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2019-MDD/QS-054

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll. certifies that the medical device of Class IIa.

Dental Unit
STOMADENT IMPULS
STOMADENT NEO
STOMADENT HARMONY

manufactured by company

STOMADENT SK s.r.o.
300, Lackovce 066 01, Slovak Republic

is manufactured under conditions fulfilling the quality system requirements of Annex VI, of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The product quality assurance has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex VI, Sections 3.3. and 4, of the Directive 93/42/EEC as amended 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310431, and the Final protocol No. 310431/2019.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Dr. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava, on September 15th, 2019

/Logotipas: 3EC International/

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakijos Respublika
Notifikuotosios įstaigos Nr. 2265

EC SERTIFIKATAS
Nr. 2019-MDD/QS-054

išleistas pagal Tarybos direktyvą 93/42/EEB, kaip atnaujinta su 2007/47/EB, kuri yra pritaikyta Slovakijos Vyriausybės dekretu Nr. 582/2008 Coll, kaip atnaujinta su 215/2013 Coll., patvirtina, kad medicinos prietaisai yra IIa klasės

Odontologinis prietaisas
STOMADENT IMPULS
STOMADENT NEO
STOMADENT HARMONY

pagamino įmonė

STOMADENT SK s.r.o.
Lackovce 188, 066 01 Humenne, Slovakijos Respublika

gamina pagal sąlygas, atitinkančias kokybės sistemos reikalavimus, pateiktus Direktyvos 93/42/EEB, kaip atnaujinta su 2007/47/EB VI Priede.

Notifikuotoji įstaiga Nr. 2265 atliko aukščiau paminėto prietaiso kokybės sistemos auditą. Buvo įvertinta pilna kokybės užtikrinimo sistema ir rasta, kad atitinka paminėtus reikalavimus. Kokybės sistema gali būti nuolat tikrinama pagal Direktyvą 93/42/EEB, kaip atnaujinta su 2007/47/EB. Detalus sistemos, reikalavimų ir būtų, kuriuos taiko gamintojas, aprašymas yra pateiktas Audito ataskaitoje Nr. 310431 ir Galutiniame protokole Nr. 310431/2019.

Šis sertifikatas išleistas pagal šias sąlygas:

Taikomas tik kokybės sistemai, kurią taiko gamintojas aukščiau paminėtiems medicininių prietaisų modeliams ir nepakeičia dizaino ar tipo tyrimo procedūrų, jei reikalaujama. Sertifikatas galioja kol nepakeičiamos kokybės sistemos gaminimo sąlygos, bet ilgiausiai iki 2024 m. gegužės 26 d. Sertifikato galiojimas priklauso nuo reguliarių priežiūros auditų teigiamų rezultatų ir atitikimo atitinkamiems įstatymams ir kitiems gamintojo reikalavimams.

/Antspaudas/

/Parašas/
Dr. Katerina Tomin Srdošova
Atsakinga už dokumentą ir NB 2265 vardu

Bratislava, 2019 m. rugsėjo 15 d.

Vertėjas Šiutas Bartaševičius

VERTIMAS TIKRAS

Viešųjų pirkimų specialistė
Aušra Silickienė

ITALIANO

1. ISTRUZIONI D'USO PER L'ODONTOIATRA/PARAMEDICO

• 1.1 GENERALITÀ

La "SIRINGA MINIMATE" è un dispositivo ad uso esclusivamente odontoiatrico, nato con lo scopo di insufflare aria ed acqua (da sole o combinate) per mantenere costantemente pulito ed asciutto il campo operatorio.

• 1.2 CARATTERISTICHE GENERALI

La SIRINGA MINIMATE è stata progettata con i più moderni concetti ergonomici per un facile uso ed una immediata pulizia e sterilizzazione. Sia il puntale che l'impugnatura sono facilmente estraibili per una perfetta disinfezione e sterilizzazione in autoclave a 135°C. Sono disponibili pertanto più impugnature di forma diversa: il dentista può scegliere la forma che preferisce in base alla necessità: a gomito o a stilo.

• 1.3 MARCATURA CE

Ogni prodotto è marcato CE.

2 DATI IDENTIFICATIVI E GARANZIA

• 2.1 LOTTO DI COSTRUZIONE

Ogni prodotto è caratterizzato da un numero riportato all'interno della parte terminale, numero che identifica univocamente il lotto di produzione. Mediante questo numero è sempre possibile rintracciare il periodo di costruzione e le relative schede di controllo.

• 2.2 GARANZIA

Il prodotto è garantito dalla nostra società per 12 mesi dalla data del documento di consegna. Qualsiasi manipolazione o modifica non autorizzata, oltre a far decadere immediatamente la garanzia, solleva la nostra società da ogni responsabilità per danni a persone, animali o cose che potrebbero verificarsi in conseguenza di tale manomissione. Per ogni controversia il Foro competente è quello di Milano (Italy).

3 CARATTERISTICHE TECNICHE

Pressione acqua di alimentazione max	Bar	2,5
Pressione di alimentazione aria max	Bar	4,5
Portata aria	Nl/min	10
Portata acqua	Cc/min	110

4 INSTALLAZIONE E COLLEGAMENTI

• 4.1 Data la natura dello strumento l'installazione e riparazione deve essere eseguita SOLO dal fabbricante di riuniti o da un suo tecnico autorizzato (il fabbricante di riuniti è dotato di un apposito manuale di installazione).

5 USO NORMALE

• 5.1 Per insufflare acqua fredda nel campo operatorio basta premere il pulsante sinistro dell'impugnatura.

• 5.2 Per insufflare aria fredda nel campo operatorio basta premere il pulsante destro dell'impugnatura.

• 5.3 Per insufflare acqua ed aria fredde in modo combinato (spray), basta premere contemporaneamente i due pulsanti dell'impugnatura.

6 PULIZIA E STERILIZZAZIONE

Dopo ogni intervento su un paziente si deve, al fine di garantire la massima igiene, pulire e sterilizzare la siringa. A tal fine occorre eseguire le fasi seguenti.

- staccare il puntale (svitando il terminale ferma punta) e/o l'impugnatura completa (premendo il pulsante posto nella parte inferiore della stessa e tirando verso l'alto).
- pulirli con un panno pulito, rimuovendo eventuali macchie.
- porli in autoclave a vapore d'acqua a 135 °C 4 minuti minimo.

7 MANUTENZIONE

Non è prevista ne necessaria alcuna manutenzione specifica dell'apparecchio, se non la normale pulizia e sterilizzazione descritte al punto precedente. Ogni operazione di lubrificazione è da escludere in quanto può causare danni irreparabili alla siringa.

8 SMALTIMENTO E ROTTAMAZIONE

Il prodotto non contiene componenti pericolosi o tossico-nocivi, né viene in contatto con prodotti di questo tipo durante il ciclo di lavoro.

9 SEGNALAZIONE ANOMALIE

Per il soddisfacimento dei requisiti di conformità alla dir. 93/42 CEE, l'azienda ha istituito una procedura di sorveglianza post-vendita su eventuali problemi generati dall'utilizzo dei nostri prodotti. Vi chiediamo gentilmente di segnalarci eventuali anomalie inviandoci il tagliando sottostante.

SCHEDA SEGNALAZIONE ANOMALIE SIRINGA MINIMATE

Prodotto _____

Tipo _____

Tipo di segnalazione: ☐ Anomalia ☐ Suggerimento

Descrizione

_____

_____

_____

_____

Data _____

Società _____

Indirizzo _____

_____

_____

Spedire a: LUZZANI DENTAL SRL - VIA TORINO, 3
SENAGO (MI) ITALY
oppure spedire al seguente fax: +39 0299010379
e-mail: info@luzzani.com

ENGLISH

1. DIRECTIONS FOR USE BY DENTIST/PARAMEDIC

• 1.1 INTRODUCTION

The "MINIMATE SYRINGE" is a device for dental use only, designed to insufflate air and water (separately or combined) to keep the operating field constantly clean and dry.

• 1.2 GENERAL CHARACTERISTICS

The MINIMATE SYRINGE is designed on the basis of the latest ergonomic concepts for easy use and immediate cleaning and sterilisation. The tip and the handpiece are easily removed for perfect disinfection and sterilisation in the autoclave at 135°C.
Handpieces of different shapes are available, so the dentist can choose the preferred shape (angled or stylet) on the basis of his/her requirements.

• 1.3 CE MARKING

All products are CE.

2 IDENTIFICATION DATA AND GUARANTEE

• 2.1 MANUFACTURING BATCH

A number marked on the inside of the terminal section of each product identifies the production batch. This number can be used to trace the period of manufacture and the associated control cards.

• 2.2 GUARANTEE

The product is guaranteed by our company for 12 months from the date of the delivery document.
Any unauthorised manipulation or modification will immediately terminate the guarantee and exonerate our company from all liability for injury or damage to persons, animals or chattels that may be caused by such interference.
All disputes shall be subject to the jurisdiction of the courts of Milan (Italy).

3 TECHNICAL SPECIFICATIONS

Max. water input pressure	Bars	2.5
Max. air input pressure	Bars	4.5
Air flow rate	Nl/min	10
Water flow rate	Cc/min	110

4 INSTALLATION AND CONNECTIONS

• 4.1 In view of the nature of the instrument, installation and repairs may ONLY be performed by the dental unit manufacturer or its authorised technicians (the dental unit manufacturer holds the specific installation manual).

5 NORMAL USE

• 5.1 To insufflate cold water into the operating field, press the left-hand button on the handpiece.

• 5.2 To insufflate cold air into the operating field, press the right-hand button on the handpiece.

• 5.3 To insufflate a combination of cold air and water (spray), press the two buttons on the handpiece simultaneously.

6 CLEANING AND STERILISATION

After each use on a patient, the syringe must be cleaned and sterilised to guarantee the maximum hygiene. For this purpose, proceed as follows:

- detach the tip (by unscrewing the tip-retaining terminal) and/or the complete handpiece (by pressing the button in the lower part of the handpiece and pulling upwards).
- wipe with a clean cloth and remove any stains.
- place in a steam autoclave at 135°C for 4 minutes.

7 MAINTENANCE

No specific maintenance of the instrument is required apart from the normal cleaning and sterilisation described in the previous paragraph.
Lubrication must not be performed, as it can cause irreparable damage to the syringe.

8 DISPOSAL AND SCRAPPING

The product does not contain any dangerous or toxic/hazardous components, nor does it come into contact with such products during the operating cycle.

9 MALFUNCTION REPORTS

To meet the requirements of Directive 93/42/ECC, the company has instituted a post-marketing surveillance procedure to monitor any problems generated by the use of our products. We should therefore be grateful if you would use the form below to inform us of any malfunctions.

MINIMATE SYRINGE MALFUNCTION REPORT

Version _____

Batch _____

Type of report: ☐ Malfunction ☐ Suggestion

Description

_____

_____

_____

_____

Date _____

Signature _____

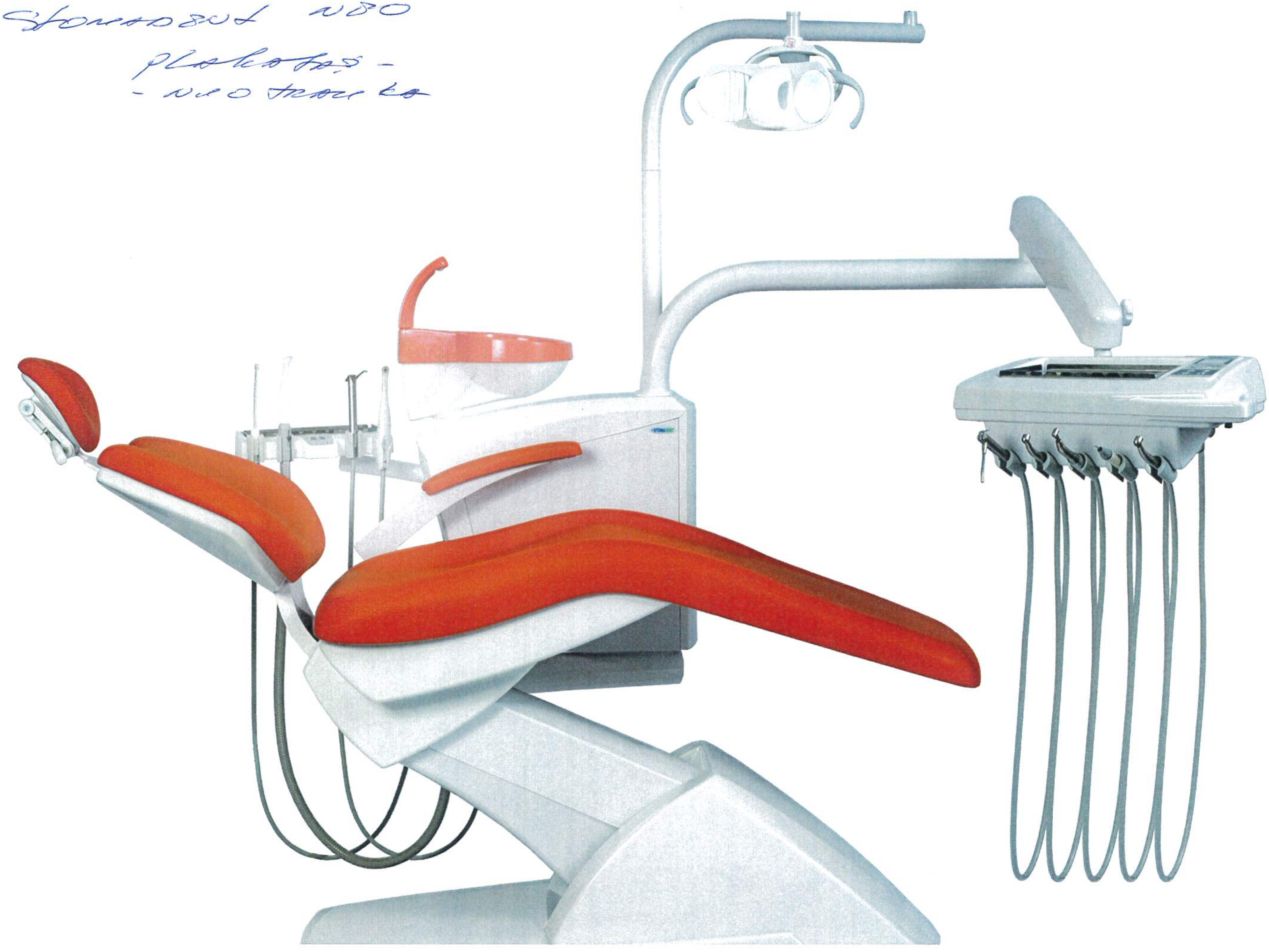
Address _____

_____

_____

Please send by post to: LUZZANI DENTAL SRL - VIA TORINO, 3
SENAGO (MI) ITALY
or fax to: +39 0299010379
e-mail: info@luzzani.com

Stomadent NEO
plakatas -
- neo tranka



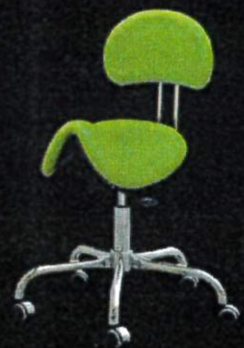
FORMEX

CLINE K

CLINE

DENTAL

DENTAL PL-K



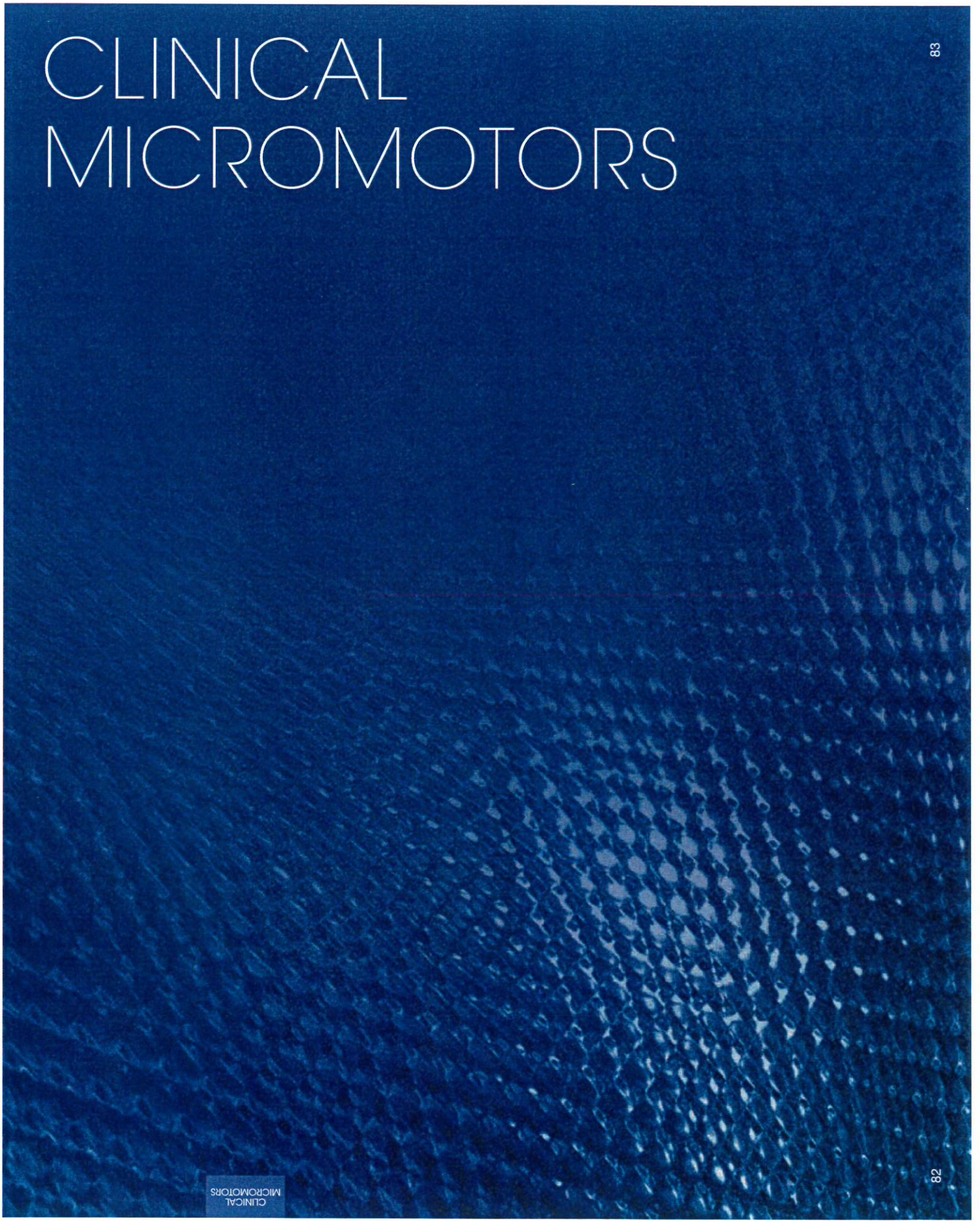
CLINE FL

ST 1123	PLU2
ST 5061	VIO2
ST 1017	ORA4
ST 5141	ORA3
ST 3096	BLU5
ST 5154	STL1
ST 3104	LBU1
ST 1210	GRN4
ST 5153	TYR1
ST 6156	
ST 6100	YEL3
ST 6021	LGY5
ST 6127	GRY1
NEFRYT	BLU6
ST 5161	GRN5
ST 7000	RED3

Please note that this colour chart is for illustration purposes only.

Katalog 8

CLINICAL MICROMOTORS



NLX plus

Optic
Internal Water Spray

Electric Micromotor Integrated System BRUSHLESS

Speed : 100 – 40,000 min^{-1}, Torque : 4.0 Ncm, with Endo Function

Features

- Torque control & Auto reverse feature 3 working modes: Auto-reverse on, Auto-stop or Auto-reverse off
- Autoclavable titanium body
- LED illumination
- Installable built-in type conforms to most dental equipments by employing original NLX BF power module

Integrated System Individual Components

MODEL **NLX BF** ORDER CODE **Y1002122**

- Power module with lamp and air function for integrated system
- Dimensions with case : W 115 x D 68.5 x H 40 (mm)

MODEL **NLS-A ADP** ORDER CODE **U1020050**

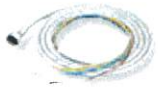
- 24 Vac - 32 Vdc converter for integrated system
- Dimensions : W 60.2 x D 81.4 x H 45.2 (mm)

MODEL **NLS-A SEL** ORDER CODE **Y1010403**

- Selector module for integrated system
- Dimensions : W 68.5 x D 56.5 x H 38.5 (mm)

MODEL **NLX plus** ORDER CODE **E1040051**

- NLX plus micromotor only (Cord not included) • Solid Titanium Body
- Autoclavable up to 135°C



MODEL **plus CD** ORDER CODE **E1040062**

- NLX plus micromotor cord for integrated system (2.2 m)

MODEL **Multi Pad** ORDER CODE **Y1001845**
MODEL **Multi Pad Auto-Select** ORDER CODE **Y1001846**

- Multi-Control Panel for built-in system
- Dimensions : W 95 x D 138 x H 31 (mm)

NBX

Optic
Internal Water Spray

Electric Micromotor Integrated System BRUSH

Speed : 60 – 40,000 min^{-1}

Integrated System Individual Components

MODEL **iMD BS** ORDER CODE **Y1002845**

- Power module for integrated system
- Dimensions : W 86 x D 57 x H 33 (mm)

MODEL **iMD SEL** ORDER CODE **Y1002848**

- Selector module for integrated system
- Dimensions : W 68.5 x D 56.5 x H 38.5 (mm)

MODEL **NBX** ORDER CODE **E1059051**

- Micromotor only (Cord not included)
- Solid Titanium Body

MODEL **NBX CDB** ORDER CODE **E1059061**

- NBX micromotor cord for integrated system

MODEL **Multi Pad** ORDER CODE **Y1001845**
MODEL **Multi Pad Auto-Select** ORDER CODE **Y1001846**

- Multi-Control Panel for built-in system
- Dimensions : W 95 x D 138 x H 31 (mm)

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60148508 0001

Report No.: 12031343 009

Manufacturer: Nakanishi Inc.
700 Shimohinata, Kanuma,
Tochigi,
322-8666 Japan

Products: Instruments and Equipment in Dental and Surgical Fields

(see attachments for products included)

Replaces Approval, Registration No.: HD 60144337 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-10-03

Date: 2020-10-03

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60148508 0001
Report No.: 12031343 009

Manufacturer: Nakanishi Inc.
700 Shimohinata, Kanuma,
Tochigi,
322-8666 Japan

Products included:

- Pneumatic dental drilling system handpiece
- Diamond dental bur, reusable
- Dental drilling system attachment
- Line-powered dental drilling system handpiece
- Pneumatic dental scaling system handpiece
- Pneumatic dental scaling system handpiece tip
- Air Motor
- Remotely-driven dental drilling system motor
- Endodontic enlarger
- Dental-professional prophylaxis motor
- Endodontic apex locator
- Dental abrasive air jet system handpiece
- Dental abrasive powder
- Sawing power tool attachment, reciprocating
- Sawing power tool attachment, oscillating

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2020-10-03

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60148508 0001
Report No.: 12031343 009

Manufacturer: Nakanishi Inc.
700 Shimohinata, Kanuma,
Tochigi,
322-8666 Japan

Products included:

- Sawing power tool attachment, sagittal
- Reciprocating surgical saw blade, reusable
- Oscillating surgical saw blade, reusable
- Sagittal surgical saw blade, reusable
- Dental implant system
- Surgical screwdriver, reusable
- Ultrasonic dental scaling system
- Ultrasonic dental scaling system handpiece tip
- Dental ultrasonic surgical system handpiece tip
- Dental ultrasonic surgical system
- Total Surgical System
- Sterile Products:
  - Sterile Drills
  - Sterile Burs
  - Sterile Blades
  - Sterile Rasps
  - Sterile Files
- Dental suction system, non-surgical

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2020-10-03

M.Sc. M. Aihara

TÜVRheinland®

Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60148508 0001
Report No.: 12031343 009

Manufacturer: Nakanishi Inc.
700 Shimohinata, Kanuma,
Tochigi,
322-8666 Japan

Products included:

- Pneumatic Surgical Drilling Machine
- Electric drill system for dental surgery, dental implant surgery and foot- and ankle- surgery
- External Coolant Straight Handpiece for foot surgery and oral surgery

Site included:
A1 Factory
990 Fukahodo, Kanuma, Tochigi, 322-0302, Japan

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2020-10-03

M.Sc. M. Aihara

令和３年登簿第　59　号

認　　証

嘱託人株式会社ナカニシ宮崎友美子の提出した別添証書の謄本は、その原本と対照し、原本と符合することを認めた。

よって、これを認証する。

令和３年　２　月　26　日、本公証人役場において

東京都台東区東上野１丁目７番２号

東京法務局所属

公証人　畑野隆一

Notary

HATANO Ryuji

証　　明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

令和３年　２　月　26　日

東京法務局長　山西宏紀

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
   This public document
2. has been signed by HATANO Ryuji
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of HATANO Ryuji , Notary

Certified

5. at Tokyo
6. FEB. 26. 2021
7. by the Ministry of Foreign Affairs
8. 21- №012132
9. Seal/stamp:
10. Signature

MINISTRY OF FOREIGN AFFAIRS JAPAN 外務省 日本国

Tanaka Toshie

TANAKA Toshie

For the Minister for Foreign Affairs

Registered No. 59 of 2021

NOTARIAL CERTIFICATE

This is to certify that the attached copy of the documents produced before me by MIYAZAKI Yumiko , NAKANISHI INC. exactly corresponds with the seen original.

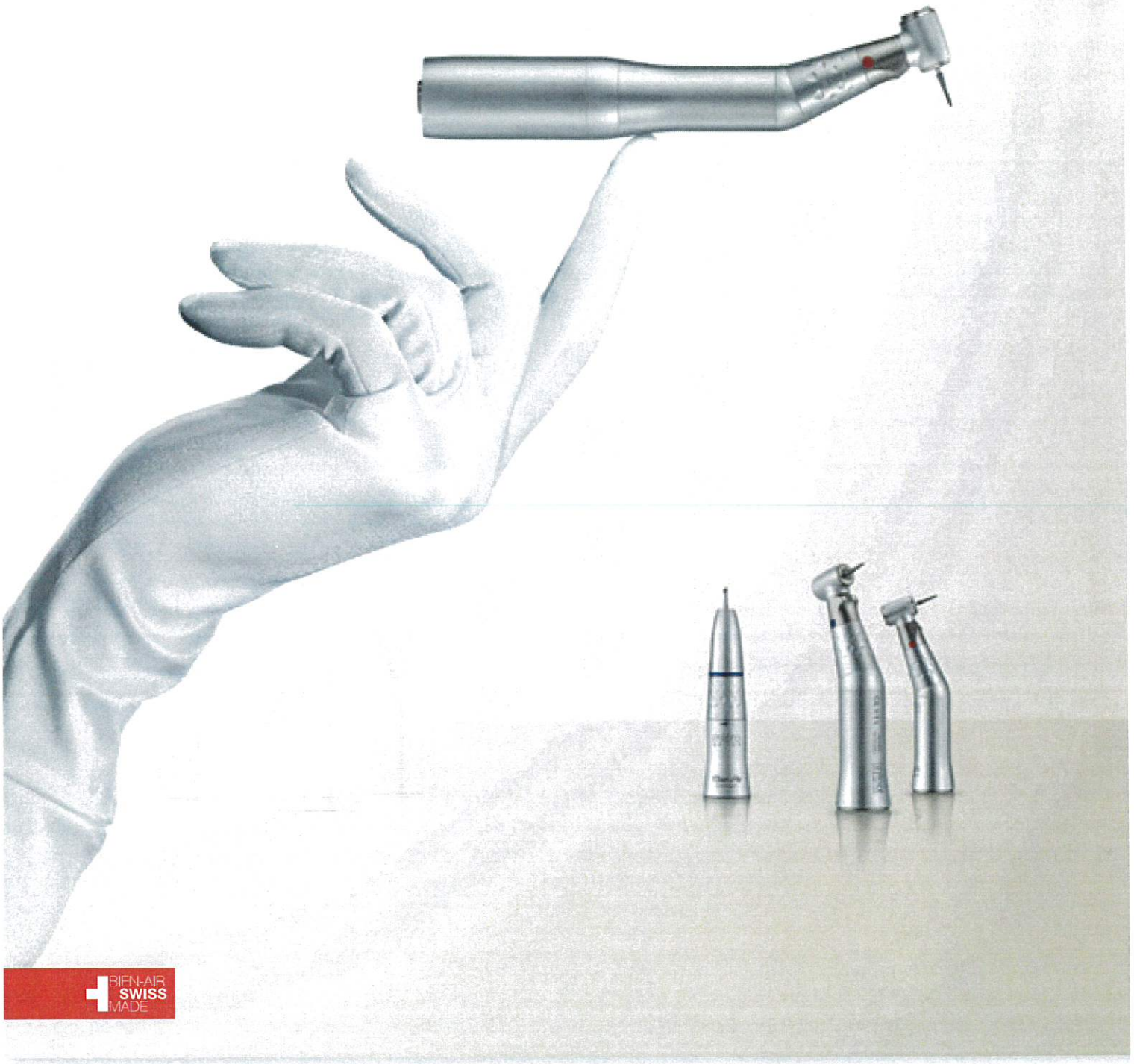
畑野隆一

Notary, HATANO Ryuji

Ueno Notary's Office of Tokyo Legal Affairs Bureau , 1-7-2 Higashiueno , Taito-ku , Tokyo, Japan

BROSURA

Bien-Air Dental



BIEN-AIR SWISS MADE

CONTRA-ANGLES AND HANDPIECES
UNFAILING PRECISION

ACCU-SPRAY

ACCU-SPRAY

Research conducted by Bien-Air engineers has clearly demonstrated the superior cooling power of six separate air and water nozzles. With the ACCU-SPRAY system, the air disperses the water to a highly precise point before contact with the bur. The ultra-precise nebulisation cools the bur and dental material as efficiently as possible. It also ensures perfect visibility in the working area. The separate water and air ducts also prevent blockages.

COOL TOUCH

COOL TOUCH

Bien-Air is the only manufacturer in the world to offer a push-button bur change mechanism with an anti-heating safety system. This reduces the risk of burning your patients with the head of your instrument. A tungsten carbide ball is placed between the pushbutton and the top of the bur locking mechanism. It absorbs heat in the event of contact when rotating. COOL TOUCH. An exclusive invention for your comfort and your patients' safety.

TECHNICAL DATA

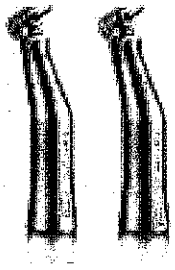
CA 1:5 L Micro-Series

Type	Contra-angle with internal spray, anti-retraction valve
Ratio	1:5 (speed increasing factor of 5)
Coupling	Compatible with Micro-Series
Locking system	Push-button bur locking with anti-heating system
Bur dimension	Bur shank Ø 1.6 mm
Light	Multi-strand optical glass conductor light
Cleaning/sterilisation	Thermal washer/steam autoclave up to 135°C (275°F)
Ref.	1600690-001

CA 1:1 L Micro-Series

Type	Contra-angle with internal spray, anti-retraction valve
Ratio	1:1 (direct)
Coupling	Compatible with Micro-Series
Locking system	Push-button bur locking
Bur dimension	Bur shank Ø 2.35 mm
Light	Multi-strand optical glass conductor light
Cleaning/sterilisation	Thermal washer/steam autoclave up to 135°C (275°F)
Ref.	1600691-001

CA 20:1 L Micro-Series / CA 20:1 L KM Micro-Series



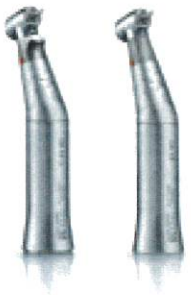
Type	Contra-angle with internal spray
Ratio	20:1 (speed reducing factor of 20)
Coupling	Compatible with Micro-Series
Locking system	Push-button bur locking
Bur dimension	Bur shank Ø 2.35 mm
Light	Multi-strand optical glass conductor light
Cleaning/sterilisation	Thermal washer/steam autoclave up to 134°C (273°F)
CA 20:1 L Micro-Series ref.	1600692-001
CA 20:1 L KM Micro-Series ref.	1600786-001

PM 1:1 Micro-Series

Type	Straight handpiece with internal spray
Ratio	1:1 (direct)
Coupling	Compatible with Micro-Series
Locking system	Locking ring
Bur dimension	Bur shank Ø 2.35 mm
Cleaning/sterilisation	Thermal washer/steam autoclave up to 135°C (275°F)
Ref.	1600693-001

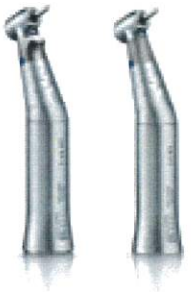
CA 1:5 L / CA 1:5

Type	Contra-angle with internal spray, anti-retraction valve
Ratio	1:5 (speed increasing factor of 5)
Coupling	E-type as per ISO 3964
Locking system	Push-button bur locking with anti-heating system
Bur dimension	Bur shank Ø 1.6 mm
Cleaning/sterilisation	Thermal washer/steam autoclave up to 135°C (275°F)
Ref. CA 1:5 L	1600386-001
Light	Multi-strand optical glass conductor light
Ref. CA 1:5	1600325-001



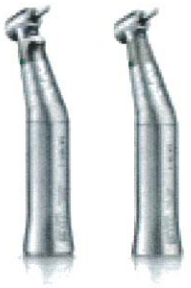
CA 1:1 L / CA 1:1

Type	Contra-angle with internal spray, anti-retraction valve
Ratio	1:1 (direct)
Coupling	E-type as per ISO 3964
Locking system	Push-button bur locking
Bur dimension	Bur shank Ø 2.35 mm
Cleaning/sterilisation	Thermal washer/steam autoclave up to 134°C (273°F)
Ref. CA 1:1 L	1600384-001
Light	Multi-strand optical glass conductor light
Ref. CA 1:1	1600424-001



CA 10:1 L / CA 10:1

Type	Contra-angle with internal spray
Ratio	10:1 (speed reducing factor of 10)
Coupling	E-type as per ISO 3964
Locking system	Push-button bur locking
Bur dimension	Bur shank Ø 2.35 mm
Cleaning/sterilisation	Thermal washer/steam autoclave up to 134°C (273°F)
Ref. CA 10:1 L	1600385-001
Light	Multi-strand optical glass conductor light
Ref. CA 10:1	1600425-001



CAP 15:1 Prophy

Type	Contra-angle without light or spray, screw or clip cup interchangeability
Ratio	15:1 (speed reducing factor of 15)
Cleaning/sterilisation	Thermal washer/steam autoclave up to 134°C (273°F)
Ref.	1600290-001

PMP 10:1 Prophy

Type	Handpiece without light or spray, for standard disposable heads
Ratio	10:1 (speed reducing factor of 10)
Cleaning/sterilisation	Thermal washer/steam autoclave up to 134°C (273°F)
Ref.	1600289-001

CA 1:1 HERITAGE OF RELIABILITY.

There are some devices still earning respect and admiration forty years in, and Bien-Air's classic CA 1:1 and CA 1:5 electric handpieces are two of them. Forever evolving, their dominating productivity and remarkable durability make them the most popular models in the lineup. The series' fully redesigned bur-locking and rotation drive mechanism ensures micron-precise concentricity and stability, while a 60 to 200,000 rpm speed range lets you complete the most intricate restorative work with incredible accuracy – and on your own terms. CA 1:1 and CA 1:5 epitomize the reliability and quality Bien-Air has built its reputation on.

Reference:
CA 1:1 L Standard 1600384-001
CA 1:1 L Micro-Series 1600691-001
CA 1:1 Standard 1600424-001

TECHNICAL DATA

	CA 1:1 L Standard	CA 1:1 L Micro-Series	CA 1:1 Standard
Transmission ratio	1:1	1:1	1:1
Maximum speed (rpm)	40'000	40'000	40'000
Head	-	-	-
Head diameter (mm)	9.8	9.8	9.8
Head size (mm)	15.3	15.3	15.3
Weight (g)	86	79	88
Noise level (dBa)	57	57	57
Spray system	2x3 separate air/water sprays	2x3 separate air/water sprays	2x3 separate air/water sprays
Lighting system	Multi-strand optical glass technology	Multi-strand optical glass technology	-
Anti-heating system	-	-	-
Coupling system	ISO 3964 & Bien-Air Micro-Series	ISO 3964 & Bien-Air Micro-Series	ISO 3964 & Bien-Air Micro-Series
Warranty	2 to 3 years[1]	2 to 3 years[1]	2 to 3 years[1]
Reference	CA 1:1 L Standard 1600384-001	CA 1:1 L Micro-Series 1600691-001	CA 1:1 Standard 1600424-001

CA 1:1 L Standard

Transmission ratio	1:1
Maximum speed (rpm)	40'000
Head	-
Head diameter (mm)	9.8
Head size (mm)	15.3
Weight (g)	86
Noise level (dBa)	57
Spray system	2x3 separate air/water sprays
Lighting system	Multi-strand optical glass technology
Anti-heating system	-
Coupling system	ISO 3964 & Bien-Air Micro-Series
Warranty	2 to 3 years[1]
Reference	CA 1:1 L Standard 1600384-001

CA 1:1 L Micro-Series

Transmission ratio	1:1
Maximum speed (rpm)	40'000
Head	-

Head diameter (mm)	9.8
Head size (mm)	15.3
Weight (g)	79
Noise level (dBa)	57
Spray system	2x3 separate air/water sprays
Lighting system	Multi-strand optical glass technology
Anti-heating system	-
Coupling system	ISO 3964 & Bien-Air Micro-Series
Warranty	2 to 3 years[1]
Reference	CA 1:1 L Micro-Series 1600691-001

CA 1:1 Standard

Transmission ratio	1:1
Maximum speed (rpm)	40'000
Head	-
Head diameter (mm)	9.8
Head size (mm)	15.3
Weight (g)	88
Noise level (dBa)	57
Spray system	2x3 separate air/water sprays
Lighting system	-
Anti-heating system	-
Coupling system	ISO 3964 & Bien-Air Micro-Series
Warranty	2 to 3 years[1]
Reference	CA 1:1 Standard 1600424-001

[1] 2-year standard warranty and 1-year optional warranty available through Bien-Air's PlanCare extended warranty program.

Bien-Air Medical Technologies develops, manufactures, and markets instrumentation devices and systems across multiple dental and surgery specialities. The company operates eight subsidiaries from its Bienne, Switzerland headquarters and is backed by a solid network ...

Information

Where to buy?

Where to repair?

Maintenance of the products

Privacy

General Terms and Conditions

Certificates of Quality

Newsletter

Keep up on our always evolving product features and technology. Enter your e-mail and subscribe to our newsletter.

Email Address

Contact Us

Bien-Air Dental SA
Länggasse 60
Case Postale
CH-2500 Bienne / Suisse

Phone: +41(0) 32 344 64 64
Fax: +41(0) 32 344 64 91
Email: office@bienair.com

created by Ide

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 065560 0002 Rev. 01

Manufacturer:

Bien-Air Dental SA
Länggasse 60
2504 Biel/Bienne
SWITZERLAND

Product Category(ies): **Air and electrical motors, straight and contra-angle handpieces, turbines, air and electrical hoses and couplings and electronic consoles for: dental applications, oral and maxillofacial surgery**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713176166

Valid from: 2020-04-29
Valid until: 2024-05-26

Date, 2020-04-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ORIGINAL

LETTER OF AUTHORIZATION

To whom it may concern

Bienne, February 25th 2016

We, Bien-Air Dental S.A. located in Länggasse 60, case Postale , CH-2500 Bienne 6, Switzerland hereby confirm that the company:

Medical Trade, s.r.o
Kreslicka 1
101 00 Prague 10
Czech Republic

is an authorized sales and service partner for all the Bien-Air Dental products in the Czech Republic.

With best regards.

Michel NOEL
Sales Manager

Bien-Air Dental SA
Länggasse 60
Case postale
CH-2500 Bienne 6

Bien-Air Dental SA
Länggasse 60 P.O. Box 6008 CH-2500 Bienne 6 Phone +41 (0)32 344 64 64 Fax +41 (0)32 344 64 91 dental@bienair.com www.bienair.com

NR. 1.

MEDICAL TRADE

Prague, April 19th 2021

To whom it may concern

We, Medical Trade, s.r.o., located in Křeslická 301/1, 101 00 Prague 10, Czech Republic,

as an authorized **sale and service partner for all Bien-Air Dental S. A. products in the Czech Republic,**

hereby confirm

that **CA 1:5 (L) and CA 1:1 (L) contra-angles,** produced by Bien-Air Dental S. A., are equipped with **internal cooling system and 2 x 3 separate air/water sprays.**

With best regards

Ing. Vladimír Valenta
Executive Director

MEDICAL TRADE s.r.o
Křeslická 1, 101 00 Praha 10
Tel.: 272 765 043
IČO: 25790579, DIČ: CZ25790579

Medical Trade, s. r. o.
Křeslická 1
101 00 Prague 10
Czech Republic
Tel.: +420 602 350 661

Nr. 2.

MEDICALTRADE

Prague, April 8th 2021

To whom it may concern

We, Medical Trade located in Křeslická 301/1, 101 00 Prague 10, Czech Republic,

who are **sale and service partner for all Bien-Air Dental S. A. products in the Czech Republic,**

hereby confirm that following **Bien-Air Dental S. A. turbines and handpieces are sterilizable in Class B autoclaves up to 135°C:**

All versions of turbines: **Bora, Prestige, Tornado**

All versions of contra-angles: **CA 1:5 (EVO), CA 1:1 (EVO), CA 10:1, CA 20:1**

All versions of straight handpieces: **PM 1:1**

With best regards

Bc. Martina Pokrývková Valentová
Export Sales Manager

Medical Trade, s. r. o.
Křeslická 1
101 00 Prague 10
Czech Republic
Tel.: +420 724 380 730

MEDICALTRADE® s.r.o.
Křeslická 1, 101 00 Praha 10
Tel.: 272 765 043
IČO: 25790579 DIČ: CZ25790579

MK-dent

COLLECTION

2019 / 2020

TURBINES CLASSIC LINE

	MK-DENT CLASSIC LINE, POWER EDITION, LUX	MK-DENT CLASSIC LINE, STANDARD HEAD, LUX	MK-DENT CLASSIC LINE, POWER EDITION	MK-DENT CLASSIC LINE, STANDARD HEAD	MK-DENT CLASSIC LINE, SMALL HEAD, LUX	MK-DENT CLASSIC LINE, SMALL HEAD
Reference Number	HC20KL	HC21KL	HC20K	HC21K	HC22KL	HC22K
Light	√	√	-	-	√	-
Head Size	Standard head	Standard head	Standard head	Standard head	Small head	Small head
Head Dimensions (mm)	Ø 12.5 x H 14.3	Ø 12.5 x H 14.3	Ø 12.5 x H 14.3	Ø 12.5 x H 14.3	Ø 10.8 x H 12.5	Ø 10.8 x H 12.5
Coupling Type	Kavo	Kavo	Kavo	Kavo	Kavo	Kavo
KEY FEATURES						
Bur Guide	Carbide insert	Carbide insert	Carbide insert	Carbide insert	Carbide insert	Carbide insert
Back Cap	Push button	Push button	Push button	Push button	Push button	Push button
Bearing	Ceramic	Ceramic	Ceramic	Ceramic	Ceramic	Ceramic
Spray Outlet	4 asymetrical mixed	4 asymetrical mixed	4 asymetrical mixed	4 asymetrical mixed	3 asymetrical mixed	3 asymetrical mixed
TECH SPECS						
Power (W)	28	23	28	23	18	18
Non-load Speed (rpm)	375 000	375 000	375 000	375 000	420 000	420 000
Sound Level (db)	Max. 57	Max. 57	Max. 57	Max. 57	Max. 60	Max. 60
Weight (g)	63	63	63	63	63	63
Tubing	6-pin	6-pin	4-pin	4-pin	6-pin	4-pin
Coupling	QC6016KW (LED) QC6016K (LED) QC5016KW (Xenon) QC5016K (Xenon)	QC6016KW (LED) QC6016K (LED) QC5016KW (Xenon) QC5016K (Xenon)	QC4014K QC4012K	QC4014K QC4012K	QC6016KW (LED) QC6016K (LED) QC5016KW (Xenon) QC5016K (Xenon)	QC4014K QC4012K
Warranty (months)	18	18	18	18	18	18

Nr. 1.

BARGTEHEIDE, 18.08.2021

MK-dent

Marie-Curie-Str. 2, 22941 Bargteheide Germany

To whom it may concern,

We, the MK-dent GmbH, located in Marie-Curie-Strasse 2 in 22941 Bargteheide GERMANY, confirm that our turbines fulfill the criteria of internal water-air cooling across the entire product range.

Please feel free to contact us for further information

With kind regards

FABIAN KLEENE
VICE PRESIDENT - MARKETING & SALES
MK-DENT GMBH

+49 4532 400 49 42
FA.KLEENE@MK-DENT.COM

Nr. 2.

MK-dent GmbH, Marie-Curie-Str. 2, 22941 Bargteheide, Germany

Bargteheide, 20.03.2020

Product confirmation

To whom it may concern, We, MK-dent GmbH located at Marie-Curie-Strasse 2 in 22941 Bargteheide in Germany, confirm that our manufactured dental turbines and contra angles are:

1) compressed air driven,
2) connected to sleeve according to ISO standard Ritter / Midwest,
3) can be autoclaved in Type B autoclaves.

MK-dent® GmbH
Marie-Curie-Straße 2
D - 22941 Bargteheide
Tel. 0 45 32 / 400 49-0 Fax 0 45 32 / 400 49-10

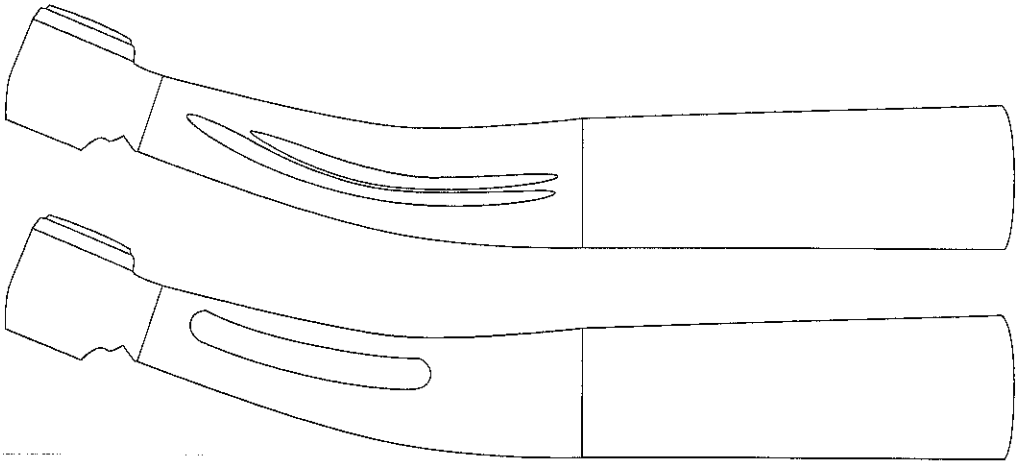
Martin Kryniecki
Partner Development Manager
MK-dent GmbH

MK-dent GmbH	**Phone:**	+49 (0)4532 40049-0	**Bank:**	Hamburger Sparkasse	Amtsgericht Ahrensburg 90 HRB 4272	
Marie-Curie-Str. 2	**Fax:**	+49 (0)4532 40049-10	**Swift Code**	HASP DE HHXXX		Michael Kleene
22941 Bargteheide	**E-mail:**	info@MK-dent.com	**Bank Code:**	200 505 50	**VAT-No.:**	DE207950833
Germany	**Internet:**	www.MK-dent.com	**Account No.:**	1354/120436	**TAX-No.:**	30 293 2502 9

MK-dent® GERMANY

Instruction manual

HP21KL, HP21WL, HP21SL, HP21NL, HP22KL, HP22WL, HP22SL, HP22NL
HC20K/KL, HC21K/KL, HC21W/WL, HC21S/SL, HC21N/NL, HC22K/KL, HC22W/WL, HC22S/SL, HC22N/NL



CE 0123

1 Explanation of symbols

	See chapter **2. Safety**
	Important information for the user
	Product can be sterilized in a steam sterilizer (Autoclave)
	Can be used in thermal disinfectors
CE	CE-mark – Confirms that this product fulfills all requirements for medical products
REF	Reference number
SN	Serial number

2 Safety

2.1 Description of danger levels

	**CAUTION**
	CAUTION is used if a deficiency in adequate care may result in an endangering of the patient, the user or others.

	**WARNING**
	WARNING is used if improper use may result in serious injuries.

2.2 Safety notes

	**WARNING**
	Risk of injury for the patient and the operator Concerning damages like irregular running noise, irregular vibrations, an unspecific rise in temperature and/or other defects. -> Stop operating immediately and contact our service.

	**WARNING**
	Risk of infection In case of an injury of the tissue in the oral area, do not proceed to work with air-operated instruments because of a high risk of an infection.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 05 51317 005

Manufacturer:

MK-dent GmbH
Marie-Curie-Straße 2
22941 Bargteheide
GERMANY

Facility(ies):

MK-dent GmbH
Marie-Curie-Straße 2, 22941 Bargteheide, GERMANY

Product Category(ies):

Turbines, high and low speed handpieces, prophylaxis handpieces, motors and couplings including spare parts and accessories for the dental area

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: 713132582

Valid from: 2018-08-05
Valid until: 2023-08-04

0405276736725O

Date, 2018-06-08

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

MK-dent GmbH, Marie-Curie-Str.2, 22941 Bargteheide, Germany

Bargteheide ,01.06.2020

Letter of Authorization

This is to certify that
MK-dent GmbH
Marie-Curie-Strasse 2
22941 - Bargteheide
Germany

Appoints
Limeta Jsc
Graiciuno Str. 4
02241 Vilnius
Lithuania

, as an authorized dealer for importation, distribution and repairs of **MK-dent** products in:

Lithuania

This appointment is effective since 01.06.2020**.** This contract is valid for 1 year from the date of issue and it is automatically renewed year by year unless cancelled by one of both parties at least 30 days before each natural expiry.

MK-dent GmbH

.....
(authorized signature)

Fabian Kleene
Vice President
Sales & Marketing

MK-dent GmbH	**Phone:**	+49 (0)4532 40049-0	**Bank:**	Hamburger Sparkasse	Amtsgericht Ahrensburg 90 HRB 4272		
Marie-Curie-Str.2	**Fax:**	+49 (0)4532 40049-10	**Swift Code**	HASP DE HHXXX		Michael Kleene	
22941 Bargteheide	**E-mail:**	info@mk-dent.com	**Bank Code:**	200 505 50	**VAT-No.:**	DE207950833	
Germany	**Internet:**	www.mk-dent.com	**Account No.:**	1354/120436	**TAX-No.:**	30 293 2502 9	

mectron

PRODUCT CATALOGUE

2021

TECHNICAL DATA

operating frequency:
24.000 – 36.000 Hz
power types:
adjustable via the dental chair
power supply:
24 VAC, 50-60 Hz / 32 VDC
water supply:
via the dental unit

warranty:
2 years, handpiece 1 year

COMPACT PIEZO LED

Equipment set
1 electronic module
1 LED ultrasonic handpiece
1 basic kit equipped with: scaling inserts S1 and S6, perio inserts P1 and P10

Ref. no. 05090008

COMPACT PIEZO P2K

Equipment set
1 electronic module
1 ultrasonic handpiece
1 basic kit equipped with: scaling inserts S1, S2, S3 and 1 high-efficiency scaling insert S6

Ref. no. 05090003

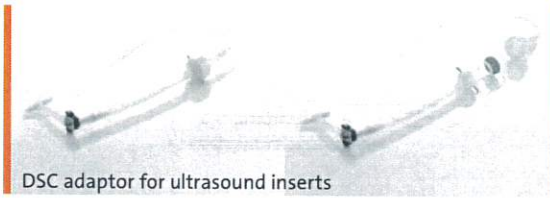
COMPACT PIEZO LED
COMPACT PIEZO

Compact efficiency or directly built-in.

Including feedback-system for constant power.

SPARE PARTS

High quality spare parts for your ultrasound device.



DSC adaptor for ultrasound inserts

scaler insert adaptor

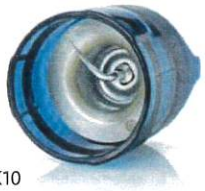
ADAPTORS FOR THERMODISINFECTION

Product	Ref. no.
DSC Adaptor (for scaler handpiece irrigation line) *	04610007
Spare filter for DSC Adaptor *	04590006
Scaler insert Adaptor *	04610009

COMMON SPARE PARTS

dynamometric torque wrench K10	02900137-001
dynamometric torque wrench K6	02900074
dynamometric wrench K7 (for tipholder DB1)	02900081
water filter	00420004
insert tray	02900072
universal cart	03540011
universal cart with water & air connections	03540012

* not disposable



dynamometric torque wrench K10

dynamometric torque wrenches K6 and K7

water filter

every insert is supplied with its own torque wrench

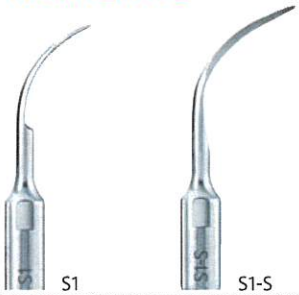
SCALING INSERTS

Product	Ref. no.
insert S1	02960001-001
universal curette with semicircular diameter for considerable tartar removal	
insert S1-S	02960009-001
slim universal curette with triangled slightly curved surface for removal of supragingival tartar, subgingival concrements and biofilm	
insert S2	02960002-001
universal curette with triangled, slightly curved surface, efficient in the interdental spaces and posterior surfaces	
insert S3	02960003-001
flat, with rounded edges for considerable supragingival tartar removal	
insert S4	02960004-001
universal curette with 45° angled, triangled and slightly curved surface for tartar removal on mesial and distal interdental surfaces in the posterior area	
insert S5	02960005-001
similar shape to S1 insert but longer and thinner for gentle supra- and subgingival tartar removal and for gingivitis	

INSERTS

For a wide range of applications

SCALING



SCALING HIGH EFFICIENCY

S6

S7

S8

→ every insert is supplied with its own torque wrench

→ SCALING HIGH EFFICIENCY INSERTS

Product	Ref. no.
insert S6	02960006-001

contra-angled universal curette with semicircular diameter, powerful insert (twice the power of S1 insert) for considerable tartar removal

insert S7	02960007-001

contra-angled universal curette with triangled, slightly curved surface, powerful insert (twice the power of S2 insert) efficient in the interdental spaces and posterior surfaces

insert S8	02960008-001

contra-angled, flat working surface with round edges, powerful insert (twice the power of S3 insert) for considerable supragingival tartar removal

mectron
medical technology

Mectron S.p.A.
Via Loreto, 15/A
16042 Carasco - GE (Italy)
Tel. +39 0185 35361
Fax +39 0185 351374

P.IVA IT00177110996
N. Iscr. Reg. Imprese Genova
e C.Fisc.: 01126960101
R.E.A. Genova 253624
www.mectron.com
mectron@mectron.com

DICHIARAZIONE DI CONFORMITA'

Nome dispositivo: COMPACT PIEZO LED

Numero di serie / serial number: 108003863

Tipologia / Typology: Ablatore ad Ultrasuoni/Ultrasonic Scaler

La Ditta Mectron S.p.A., fabbricante delle tipologie di dispositivi medici:
"Dispositivi per chirurgia ossea, Ablatori ad Ultrasuoni, Apparecchi combinati ablatore e rimozione della placca, Apparecchi per la rimozione della placca, Lampade Polimerizzatrici ed Inserti per chirurgia ossea", dichiara sotto la propria responsabilità che tali apparecchi soddisfano le disposizioni applicabili delle seguenti direttive e dei corrispondenti decreti di attuazione:

a) Direttiva 93/42/CEE - recepita in Italia con D.Lgs n. 46 del 24-2-1997, modificata dalla Direttiva 2007/47/CEE - recepita in Italia con D.Lgs n. 37 del 25-1-2010.

Mectron S.p.A., manufacturer for the following Medical Devices:
"Bone surgery units, Ultrasonic Scalers, Ultrasonic Scalers and Jet-Cleaner Polishers, Jet-Cleaner Polishers, Light Curing Units and Inserts for bone surgery", declares on its responsibility that those apparatus comply with the applicable requirements of the following directives:

a) Directive 93/42/EEC - D.Lgs. 24 February 1997 n. 46, amended by Directive 2007/47/EEC - D.Lgs. 25 January 2010 n. 37.

A tale scopo Mectron S.p.A. dichiara e garantisce che:

1) Il dispositivo in oggetto soddisfa i requisiti essenziali richiesti dall'Allegato I delle Direttive menzionate al punto a);
2) La progettazione del dispositivo in oggetto soddisfa le disposizioni applicabili dell'Allegato I delle Direttive menzionate al punto a);
3) La fabbricazione soddisfa le disposizioni applicabili dell'Allegato II (Sistema Completo di Garanzia di Qualità) escluso il punto 4 delle Direttive menzionate al punto a);
4) E' garantito un sistema di Assicurazione della Qualità in conformità alla norma UNI EN ISO 9001-2015 ed UNI EN ISO 13485-2016;
5) Il dispositivo in oggetto è da considerarsi appartenente alla classe IIa.

For this purpose Mectron S.p.A. declares and guarantees that:

1) This device complies with the main requisites required by Annex I Directives listed in a);
2) The planning of this device comply with the applicable requirements of Annex I Directives listed in a);
3) The manufacture complies with the applicable requirements of Annex II (Full Quality Assurance System) without point 4 of the Directives listed in a);
4) A system of Quality Assurance is guaranted in conformity with the UNI EN ISO 9001-2015 and UNI EN ISO 13485-2016;
5) This device is to be considered as belonging to the class IIa.

Si dichiara pertanto che i dispositivi in oggetto sono conformi a quanto prescritto dalle Direttive menzionate al punto a), con approvazione dell'Ente Notificato e sono stati immessi in commercio con la marcatura CE, secondo quanto disposto dall'Articolo 17 delle suddette Direttive e Articolo 16 del D.Lgs n. 37 del 25-01-2010.

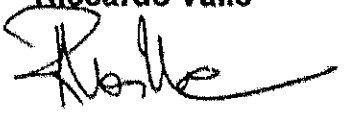
Therefore we declare that this device complies with all that is prescribed by the Directives listed in a), with approvation of Notified Body and they have been put on the market with the EEC mark according to the Article 17 of the above-mentioned Directives and Article 16 of D.Lgs. 25 January 2010 n. 37.

Ente: KIWA CERMET ITALIA 0476
Via Cadriano 23

Certificato: MED 21014A

Data / Date: 02/07/2021

Il Responsabile
Riccardo Valle



Anti-Forgery statement

Dear Users:

Thank you for trusting and supporting WOODPECKER products!

Recently we found FAKE woodpecker products on the market, due to the quality is not insured, the fake product can easily break your device and will bring potential risk for patients' safety. In order to protect our users' benefits, we particularly inform that:

1. Finding those who counterfeit and sell imitations, please email to **woodpecker@mailgl.cn** to report. **We offer 60% of the award judged** by the court to the resultful reporter, and your information will be kept strictly confidential.

2. Authenticity verification of WOODPECKER products can be checked from **www.glwoodpecker.com** and click "Anti-Forgery Query" for checking.

3. From 15th September 2012, all detachable handpiece as well as all scaling tips that sold separately are pasted with Anti-Forgery labels. Please login into our official website to check.

Scan and Login website
for more information

WOODPECKER

CURING LIGHT BUILT-IN C USER'S MANUAL

(Please read this manual before operating)

FDA CE

www.tuv.com TÜVRheinland ID:0000033514

- Certified Management System
- EN ISO 9001
- EN ISO 13485

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

www.glwoodpecker.com

Content

1. Installation

Guilin Woodpecker Medical Instrument Co., Ltd. is a high-tech enterprise in researching, developing, and producing dental equipment, and has a perfect quality assurance system, main products including ultrasonic pizeo scaler, curing light, micro motor, apex locator and ultrasurgery etc.

2. Principle and usage

2.1 BUILT-IN C adopts the principle of ray radiation to solidify the light-sensitive resin by shooting at it in a short time.

2.2 This product is used to restore teeth and solidify material for whitening teeth.

3. Structure and components

BUILT-IN C is composed mainly of high power LED, optical fiber, main unit.

4. Technical specifications

4.1 Power supply: 24V~ 50/60Hz

4.2 Rated current: 0.3A

4.3 Applied part: optical fiber

4.4 Lightsource:

4.4.1 Blue light

4.4.2 Wave length: 420nm-480nm

4.4.3 Light intensity: 1000mW/cm^2~1200mW/cm^2

4.5 Working condition:

4.5.1 Environment temperature: 5℃ to 40℃

4.5.2 Relative humidity: ≤80%

4.6 Dimensions: Φ23mm×250mm

4.7 Net weight: 160g

4.8 Consumption power: ≤8W

4.9 Protection type against electrical shock: class II

4.10 Protection against electrical shock: type B

4.11 Protection against harmful ingress of water or particular matter: Ordinary equipment (IPX0)

4.12 Safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide: not suitable under this condition.

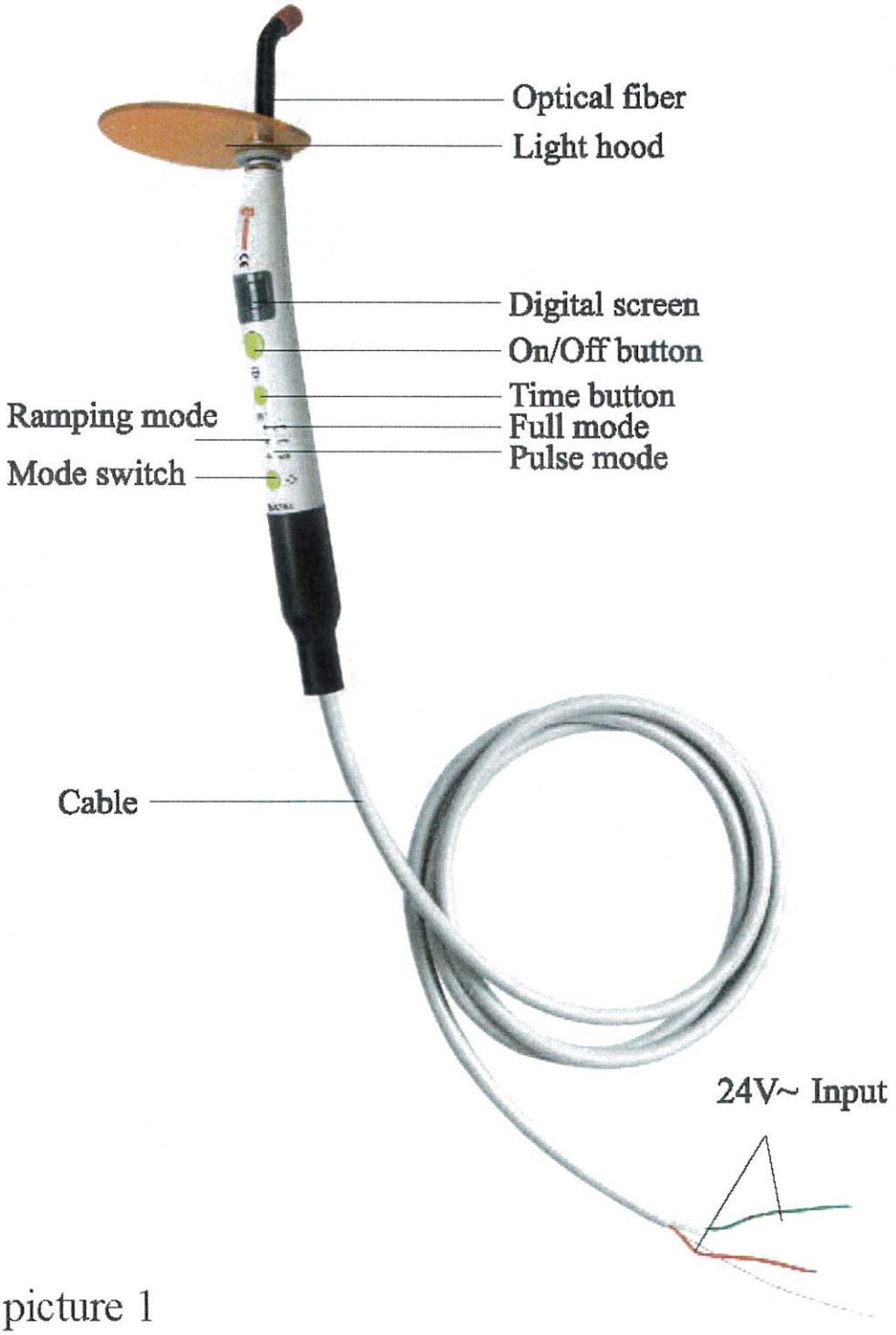
4.13 Applied part: optical fiber

Notice: the equipment needs to be installed in the medical power supply, and to ensure that the final product meets the requirements of IEC 60601-1.

5. Assembly and disassembly

5.1 Connect the power line which marked with 24V~ to the dental unit 24V~ output, lace the nylon thread to the dental unit, it's ready to be operated.

Caution: when assembling, the power of the dental unit should be cut off. The power line in the cable should be longer than the nylon thread, in case break the power line when operating.



picture 1

5.2 Take off the red cap from the optical fiber and then insert the metal part into the front of BUILT-IN C revolving, make sure to screw the fiber to the end.

5.3 To install the light hood on as show in picture 1.

5.4 Uninstall the LED, just reverse the procedure above.

6. Operation

6.1 Press the time button to choose the solidification time.4 working time modes are available: 5,10, 15, 20 seconds.

6.2 Lightly press the mode key. Following three modes are available.

6.2.1 Full power mode: blue light shine in full power.

6.2.2 Ramping mode: The power of the blue light turns from weak to stronger, and reaches the highest power in 5 seconds.

6.2.3 Pulse mode: blue light work in the mode of pulse.

6.3 During the operation, aim blue light at the position needing solidification. The machine will gives off a sound "di", when it is on. It is strong blue light after 2 seconds with week blue light. Then it counts down to "0" second to end the solidification.

6.4 After the operation, please clean the fiber with calico in order not to affect the light intensity.

6.5 The depth of solidification of composite is no less than 4mm

per 10 seconds.

6.6 The optical fiber can be spinned off by 360° and autoclaved to 135℃ and 0.22MPa.

7. Cautions

7.1 When in clinical operation, make sure the light source be aimed at the resin directly improperty position will affect the solidification.

7.2 Avoid aiming at eyes directly.

① WARNING: If the curing light works for 40s continously,the temperature of the top of optical fiber may reach 56℃.

② WARNING: Do not modify this equipment without authorization of the manufacturer.

8. Contraindications

Heart disease patients, pregnant women and children should be cautious to use this equipment.

9. Maintenance

9.1 0nly the optical fiber can be autoclaved under high temperature and pressure, other parts should be waped by clean water or disinfectants if necessary, never immersed.

9.2 After operation each time, clean the optical fiber.

10. After service

Two year warranty according to the warranty card.

11. Trouble shooting

Fault	Cause	Solution
Non-indication Non-act	1. The main unit doesn't connect well with the unit or the power doesn't on.	1. Check with the connection of the main unit and the unit. 2. Make sure the power is on.
Light intensity insufficient	1. The optical fiber is not inserted till the botton. 2. The optical fiber has cracked. 3. There is resin remained on the surface of optical fiber.	1. Insert the optical fiber again correctly. 2. Change the optical fiber. 3. Wipe off the resin.

If any malfunction case was found, please contact with the dealer the unit was purchased or our company.

12. Storage and transportation

12.1 This equipment should be handled carefully, kept away from shaking point, installed or stored at shadowy, dry, cool and

ventilated places.

12.2 Don't store it together with articles that are combustible, poisonous, caustic and explosive.

12.3 This equipment should be stored in the environment where the relative humidity is ≤80%, the atmosphere pressure is 70kPa to 106kPa and the temperature is –10℃ to +55℃.

12.4 Excess impact or shake should be avoided during transportation.

12.5 Don't mix it with dangerous articles during transportation.

12.6 Keep it away from sun or snow or rain during transportation.

13. Environmental protection

There is not any harmful element in this equipment. It can be disposed of according to the local laws.

14. Packing list

The components of the epuipment are listed in the packing list.

15. Manufacturer's right

We reserve the rights to change the design of the equipment, the technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some

differences between blueprint and real equipment, take the real equipment as the norm.

16. For technical data, please contact

EC REP Wellkang Ltd (www.CE-Marking.eu)
29 Harley St.,LONDON,W1G 9QR,UK

17. Symbol instruction

WOODPECKER Trademark

CE marked product

Type B applied part

FDA marked product

IPX0 Ordinary equipment

Class II equipment

Date of manufacture

Alternating current

Manufacturer

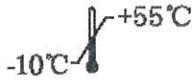
Recovery

Used indoor only

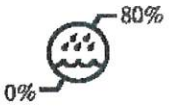
Keep dry

Screw inside/ outside

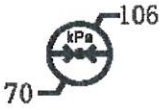
Handle with care



Temperature limitation



Humidity limitation



Atmospheric pressure for storage

Appliance compliance WEEE directive

Consult the accompanying documents

EC REP Authorised Representative in the EUROPEAN COMMUNITY

Got the quality management system certification and CE certification issued by TüV Rheinland

18. Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by WOODPECKER, any copy or fake product must take legal responsibilities.

19. Declaration of conformity

19.1 Product conforms to the following standards:

EN 60601-1:2006	EN 1041:2008
EN 60601-1-2:2007	EN ISO 14971:2009
EN 61000-3-2:2006	EN ISO 7405:2008
EN 61000-3-3:2008	EN ISO 17664:2004
EN 60601-1-4:1996	EN ISO 17665-1:2006
EN 60825-1:2007	EN ISO 10993-1:2009
EN 980:2008	EN ISO 10993-5:2009
ISO 9687:1993	EN ISO 10993-10:2010

19.2 EMC - Declaration of conformity

Guidance and manufacturer's declaration - electromagnetic emissions		
The model BUILT-IN C is intended for use in the electromagnetic environment specified below. The customer or the user of the model BUILT-IN C should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The model BUILT-IN C uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The model BUILT-IN C is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance & Declaration — electromagnetic immunity			
The model BUILT-IN C is intended for use in the electromagnetic environment specified below. The customer or the user of the model BUILT-IN C should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % U_T (>95% dip in U_T.) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95% dip in U_T.) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model BUILT-IN C requires continued operation during power mains interruptions, it is recommended that the model BUILT-IN C be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic Immunity			
The model BUILT-IN C is intended for use in.the electromagnetic environment specified below. The customer or the user of the model BUILT-IN C should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	*3V* *3 V/m*	Portable and mobile RF communications equipment should be used no closer to any part of the model BUILT-IN C, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE I At 80 MHz end 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model BUILT-IN C is used exceeds the applicable RF compliance level above, the model BUILT-IN C should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model BUILT-IN C. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the model BUILT-IN C

The model BUILT-IN C is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model BUILT-IN C can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model BUILT-IN C as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,5GHz $d=2.3\times P^{1/2}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be effected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

Scan and Login website
for more information

Guilin Woodpecker Medical Instrument Co., Ltd.
Information Industrial Park, National High-Tech
Zone, Guilin, Guangxi, 541004 P. R. China

Tel:
Europe Sales Dept.: +86-773-5873196, +86-773-2125222
North America, South America &
Oceania Sales Dept.:+86-773-5873198, +86-773-2125123
Asia & Africa Sales Dept.:+86-773-5855350, +86-773-2125896

Fax: +86-773-5822450
E-mail: woodpecker@mailgl.cn, sales@glwoodpecker.cn
Website: http://www.glwoodpecker.com

EC REP Wellkang Ltd (www.CE-Marking.eu)
29 Harley St.,LONDON,W1G 9QR,UK

ZMN/WI-04-560 2.4 Edition

WOODPECKER

Management System EN ISO 13485:2016 TÜVRheinland CERTIFIED

200 Patents; 19 invention patents; Exported to 134 countries

WOODPECKER

Since 1989

CATALOGUE

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

Spare parts for curing light

Beveled Optical Fiber

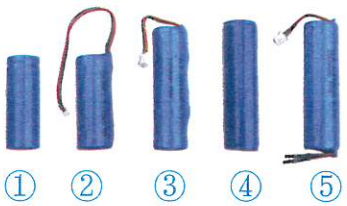
- Easy to touch any part of teeth.
- Can radiate vertically at any angles.
- Solve the problem of weak light intensity when radiate vertically with old optical fiber.
- The light intensity is 40% higher than old optical fiber on certain spot when radiate vertically.

Optical fiber

Black and white optional
Can be autoclaved under high temperature and high pressure
1#Dimensions: Φ8mm、Φ8mm / Φ5mm
2#Dimensions: Φ8mm
1#Applicable for:
LED.B, LED.C, LED.D, LED.F
LED.G, LED.P
2#Applicable for: LED.H

Power supply

Power Input:
AC100V-240V 50/60Hz
Power Output / Current:
DC5.0V / 1.0A
Applicable for:
LED.B, LED.C, LED.D
LED.F,LED.H



Battery

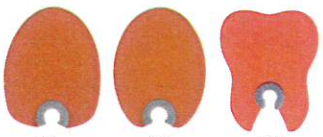
①:ICR18490A
Battery Voltage: 3.7V
Applicable for: LED.C

②:ICR18490B
Battery Voltage: 3.7V
Applicable for: LED.D

③:ICR18650A
Battery Voltage: 3.7V
Applicable for: LED.F

④:ICR18650B
Battery Voltage: 3.7V
Applicable for: LED.H

⑤:ICR18650C
Battery Voltage: 3.7V
Applicable for: LED.B



Light hood

Lightmeter

Bathymeter

Bleaching fiber for LED.F

LED lamp
3W、5W

Glasses

WOODPECKER **GUILIN WOODPECKER MEDICAL INSTRUMENT CO.,LTD.**

We GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

With legal address at INFORMATION INDUSTRIAL PARK, GUILIN NATIONAL HIGH-TECH ZONE, GUILIN, GUANGXI, P.R.CHINA

authorize STOMADENT SK s.r.o. with the legal address at: Lackovce, 300, 06601 Lackovce, Slovakia

to be our official dealer to promote, sell and provide service, install, train employees and perform warranty services the woodpecker series products manufactured by us as the part of the dental units manufactured by STOMADENT SK s.r.o.

Jason Lai

GUILIN WOODPECKER MEDICAL INSTRUMENT CO.,LTD. 桂林啄木鸟医疗器械有限公司 4503011007775

Add: Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P. R. China
Tel: +86-773-2350599,2350527 Fax: +86-773-5822450
E-mail: woodpecker@glwoodpecker.com, sales@glwoodpecker.com
Website: http://www.glwoodpecker.com

WOODPECKER

桂林市啄木鸟医疗器械有限公司
GUILIN WOODPECKER Medical Instrument Co.,LTD.

File No.: ZMN-YF-(FM-1)-01-001
Version: A

EC Declaration of Conformity

Manufacturer:

Guilin Woodpecker Medical Instrument Co., Ltd.

whose single Authorized Representative:

MedNet EC-Rep GmbH•Borkstrasse 10 • 48163 Muenster • Germany

We, the manufacturer, herewith declare that the products
Curing Light UMDNS-*Code:* 16386

MODEL: LED.B、LED.C、LED.D、LED.E、LED.F、BUILT-IN C、BUILT IN-H、LED.H、 LUX V、LED.G、LUX E、LUX VI、i Led、、X-Cure、O-Light、B-Cure

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

The product concerned has been manufactured under a quality management system according to Annex VII of Directive 93/42/EEC.

following the procedure relating to the EC Declaration of Conformity set out in Annex V and Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

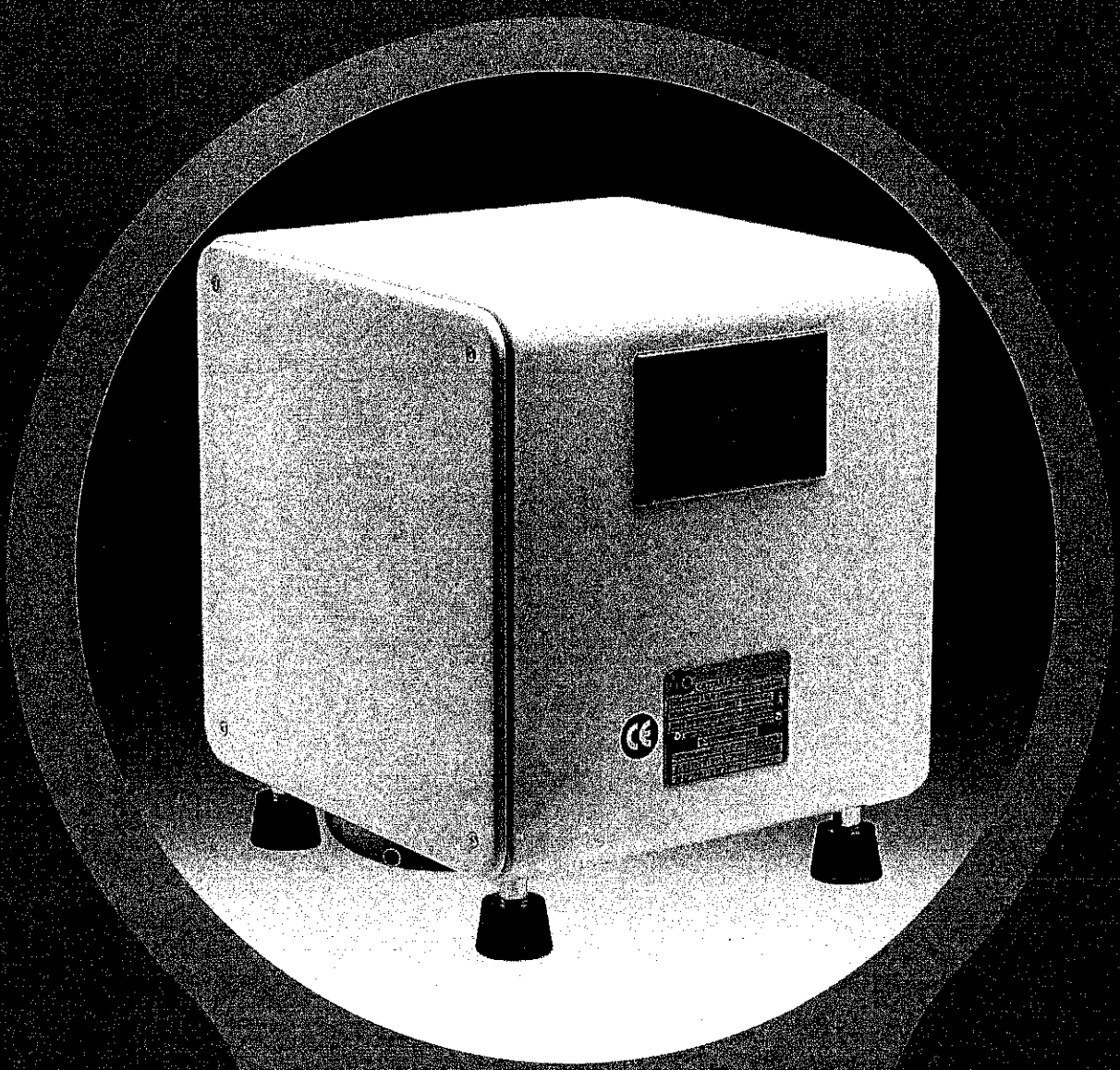
The above mentioned declaration of conformity is exclusively under the responsibility of

Company: **Guilin Woodpecker Medical Instrument Co., Ltd.**
Address: Information Industrial Park, GuiLin National High-Tech Zone, GuiLin, GuangXi, 541004, P.R.China

杨芸凤 2020.3.20
Preparation, *date*

2020.3.20
Review, *date*

2020.3.20
Legally binding signature, Function



MANUALE ISTRUZIONI
OPERATOR'S HANDBOOK
MANUEL D'UTILISATION
GEBRAUCHSANWEISUNG
MANUAL DE ISTRUCCIONES

UNI-JET 75 CARENATO

UNI-JET 75 WITH BOX
UNI-JET 75 CAPOTE
UNI-JET 75 MIT GEHÄUSE
UNI-JET 75 CARENADO

CATTANI
AIR TECHNOLOGY

• General running data Dental Aspirator

Model	Uni-Jet 75 with box and control panel
Rated voltage	230 V ∿ ± 5%
Rated frequency	50 Hz
Rated current	3,1 A
Insulation class	Class *I*
Type of appliance	B
Operating conditions	continuous operation
Protection against ingress of liquids	ordinary
Degree of protection against electric shock	type B
The motor is protected by a thermal switch	
Output power	0,4 kW
Maximum flow	1250 l/min
Maximum head for continuous operation	1300 mm H_2O
Sound pressure level	58 dB(A)*
Other voltages available on request: 240 V∿ 50 Hz 2,95 A - 220 V∿ 60 Hz 3,5 A - 120 V∿ 60 Hz 6,0 A - 110 V∿ 60 Hz 7,0 A - 100 V∿ 60 Hz 7,0 A	
This appliance cannot work in the presence of an anaesthetic mixture flammable with air, oxygen or nitrous oxide	
A bacteriological filter is also available to filtrate the exhausted air	

∿	Alternating current	IEC 417-5032
⏚	Earthing	IEC 417-5019
	Appliance Type B	IEC 878-02-02
○	OPEN (disconnected from the main electrical supply)	IEC 417-5008
I	CLOSED (connected to the main electrical supply)	IEC 417-5007
	Dangerous voltage	IEC 878-03-01

*Sound pressure level with canalized air tested according to the standard ISO 3746-1979 (E).
Parameters: r=1 - Background noise ≤ 51 dB (A) - Instrument: Brüel & Kjær Type 2232.

Manufactured by CATTANI S.P.A. - PARMA - ITALY

Air and vacuum for dentistry

Compressed air and vacuum for a wide range of medical devices located in dental surgeries and clinics, generally in class 2.4.1 in accordance with ISO 8573-1 (5 microns solid particles filtration, dry air at pressure dew point of +3°C / -20°C of atmospheric dew point, without content of oil vapors).

COMPRESSORS COMPRESSORS WITH SUCTION SUCTION ACCESSORIES

Advantages of Ekom compressors

- Oil-free air
- A wide range of air treatment accessories
- Extermely quiet operation
- Long service life
- Easy maintenance
- High durability, efficient heat removal system
- Attractive design, easy to fit into treatment rooms

00:41

Areas of use

- Dental chairs/units
- CAD/CAM systems
- Dental laboratories
- Disinfection and sterilization
- Air distribution for small and medium-sized clinics

DENTISTRY
Compressors
DK50 SIMPLE
DK50-10
DK50 PLUS
DK50 2V
DK50 2V/50
DK50 4VR/50
DK50 2X2V/110
DK50 2X4VR/110
DK50 4x2VT/M
DK50 3X4VR/M
DK50 6x2VT/M
DK50 4X4VRT/M
DK50 6X4VRT/M
DK50 9X4VRT/M
Compressors with suction
Suction
Accessories
Air for dentistry
HEALTHCARE
LABORATORY AND DIAGNOSTICS
INDUSTRY
SHEET METAL PROCESSING

DK50-10

Small-size, but powerful compressor with 10 l air tank. Performance up to 75 $l.min^{-1}$ and stable pressure up to 8 bar make it ideal for one* dental unit and other air-driven devices in a dental clinic.

PDF Leaflet

DK50-10 Z
without noise reduction cabinet

DK50-10 Z/M
without noise reduction cabinet, with dryer

DK50-10 S
with noise reduction cabinet

DK50-10 S/M
with noise reduction cabinet, with dryer

TECHNICAL PARAMETERS | DIAGRAMS | DOWNLOADS | PHOTOGALLERY

WITHOUT DRYER | WITH MEMBRANE DRYER | WITH ADSORPTION DRYER

	DK50-10 Z	DK50-10 S
Dryer	✗	
Noise reduction cabinet	✗	✓
Number of dental units	1	
Nominal voltage / frequency	230 V / 50 (60) Hz 115 V / 60 Hz	
Motor performance	0.55 kW	
Air tank capacity	10 l	
Compressor efficiency (working pressure 5 - 7 bar)	75 $l.min^{-1}$ / 5 bar (50 Hz) 85 $l.min^{-1}$ / 5 bar (60 Hz)	

EKOM spol. s r.o.
Priemyselná 5031/18
921 01 Piešťany
Slovak Republic

EC DECLARATION OF CONFORMITY (GB)

Document No: DK50/2021/EU
Article: 112000526-000

Manufacturer:
Ekom spol. s r.o.
Priemyselná 5031/18
921 01 Piešťany
Slovak Republic

SRN: P58533
Product name: COMPRESSOR
Model: DK50B, DK50BS, DK50-10Z, DK50-10Z/M, DK50-10S, DK50-10S/M, DK50 PLUS, DK50 PLUS/M, DK50 PLUS S, DK50 PLUS S/M, DK50, DK50 PLUS MOBILE, DK50 PLUS/M MOBILE, DK50 2V, DK50 2V/M, DK50 2VS, DK50 2VS/M, DK50 2V/50, DK50 2V/50/M, DK50 2V/50S, DK50 2V/50S/M, DK50 2x2V/110, DK50 2x2V/110/M, DK50 2x2V/110S, DK50 2x2V/110S /M, DK50 2V MOBILE, DK50 2V/M MOBILE, DK50 4VR/50, DK50 4VR/50/M, DK50 4VR/50S, DK50 4VR/50S/M, DK50 2x4VR/110, DK50 2x4VR/110 /M, DK50 2x4VR/110S, DK50 2x4VR/110S /M

Risk class: class I
Intended purpose: The compressor is used as a source of clean, oil-free compressed air to power active medical devices where the parameters and properties of the compressed air are suitable for the specific application.
Registration code: P68338

Noted product is in conformity with technical requirements and applicable regulations:
Regulation: MDR 2017/745
Quality Assurance Standards: EN ISO 13485:2016
Procedural Standards: EN 60601-1:2006 /A1:2013, EN 60601-1-2:2015, EN ISO 14971:2019

This declaration of conformity is issued the sole responsibility of Ekom spol. s r.o. We hereby declare that he medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical device. This declaration is supported by the Quality System approval to ISO 13485 issued by DNV GL PRESAFE AS. Certificate No. 279404-2018-AQ CZS-NA-PS Rev. 0.0 valid until: January 30, 2022.

ekom spol. s r.o. Priemyselná 5031/18 921 01 Piešťany Slovak republic

Piešťany, 26.5.2021

.....
Ing. Jozef Kováč
Regulatory Affairs Specialist

DÉCLARATION DE CONFORMITÉ CE (F)

N° de document: DK50/2021/EU
Article: 112000526-000

Fabricant:
Ekom spol. s r.o.
Priemyselná 5031/18
921 01 Piešťany
Slovak Republic

Le numéro d'enregistrement unique : P58533
Nom du produit : COMPRESSEUR
Modèle: DK50B, DK50BS, DK50-10Z, DK50-10Z/M, DK50-10S, DK50-10S/M, DK50 PLUS, DK50 PLUS/M, DK50 PLUS S, DK50 PLUS S/M, DK50, DK50 PLUS MOBILE, DK50 PLUS/M MOBILE, DK50 2V, DK50 2V/M, DK50 2VS, DK50 2VS/M, DK50 2V/50, DK50 2V/50/M, DK50 2V/50S, DK50 2V/50S/M, DK50 2x2V/110, DK50 2x2V/110/M, DK50 2x2V/110S, DK50 2x2V/110S /M, DK50 2V MOBILE, DK50 2V/M MOBILE, DK50 4VR/50, DK50 4VR/50/M, DK50 4VR/50S, DK50 4VR/50S/M, DK50 2x4VR/110, DK50 2x4VR/110 /M, DK50 2x4VR/110S, DK50 2x4VR/110S /M

Classe de risque : classe I
Usage prévu : Le compresseur est utilisé comme source d'air comprimé propre et sans huile pour alimenter les dispositifs médicaux actifs où les paramètres et les propriétés de l'air comprimé conviennent à l'application spécifique.
Code d'enregistrement : P68338

Le produit noté est conforme aux exigences techniques et aux réglementations en vigueur :
Règlement : MDR 2017/745
Normes d'assurance-qualité : EN ISO 13485:2016
Normes procédurales : EN 60601-1:2006 /A1:2013, EN 60601-1-2:2015, EN ISO 14971:2019

Cette déclaration de conformité est la responsabilité exclusive de Ekom spol. s r.o. Nous déclarons par la présente que le dispositif médical détaillé ci-dessus répond aux normes du Règlement (EU) MDR 2017/745 portant sur les dispositifs médicaux.
Cette déclaration est soutenue par l'approbation de système-qualité de l'ISO 13485 émise par DNV GL PRESAFE AS. N° de certificat 279404-2018-AQ-CZS-NA-PS Rév. 0.0 valide jusqu'au : 30 janvier 2022.

ekom spol. s r.o. Priemyselná 5031/18 921 01 Piešťany Slovak republic

Piešťany, 26.5.2021

.....
Ing. Jozef Kováč
Spécialiste des affaires réglementaires

UŽDAROJI AKCINĖ BENDROVĖ LIMETA

V.A. Graičiūno g. 4, LT-02241 Vilnius, tel. (8~5) 2649696, faks. (8~5) 2602055, el.paštas vilnius@limeta.lt
Kodas 221906050, PVM mokėtojo kodas LT219060515, Lietuvos Respublikos Juridinių asmenų registras.

VŠĮ Jonavos pirminės sveikatos priežiūros centras 2023-01-10, Nr. 2-014
Siunčiama per CVP IS

PATVIRTINIMAS
Nr. 644338

Mes UAB „LIMETA“, vadovaudamiesi įdiegta kokybės vadybos sistema, užtikriname, kad pirkimo dokumentuose vertinimo kriterijų sąlygos:

- užtikrinime papildomą garantiją 24 mėn. pratęsimą (po privalomų 24 mėn.).

Viešųjų pirkimų specialistė Aušra Silickienė