Whitening Lase Light Plus

User Manual

CE

Whitening Lase Light Plus is a device manufactured with the highest technology and all the devices are tested individually. The device has the registration at the National Health Surveillance Agency [Agência Nacional de Vigilância Sanitária], assuring this way the fulfillment of the national regulations. This device also fulfills the requirements established by the European Community, being able to be commercialized in the European market.

Whitening Lase Light Plus was developed to be used by professionals of the dental area. The dentist must be qualified to the application of the equipment's related techniques. The inadequate usage may cause irreversible damages.

⚠ The manufacturer recommends all manual reading before using the product

DEVICE FUNCTIONS

The Whitening Lase Light Plus device presents the following function:
Emits infrared laser light and blue or violet light for dental whitening.

DEVICE FUNCTIONING

The whitening handpiece has infrared lasers and blue or violet LEDs. The infrared lasers are used in the dental whitening in order to diminish the sensibility after the whitening and in order to activate the whitening gel (by heating). The blue or violet LEDs have the function of activating the whitening gel thorough the interaction of the light/dye.

INDICATION

Dental Whitening

CONTRAINDICATIONS

- Pregnant or lactating women;
- Patients with predisposition to or who have cancer;
- Patients with periodontal pathologies;
- Minimum age of 17.
- Patients with sensitive teeth.

LIMITATION

Restorations, prosthesis and exposed root are not eligible for whitening.

SPECIFICATIONS

Infrared Laser	Characteristics
Wavelength	808 nm ± 10 nm
Emitter useful power	100 mW ± 20 %

Blue or violet LED	Characteristics
Wavelength	450 nm ± 10 nm (blue) or 405 nm ± 5 nm (violet)
Emitter useful power	400 mW ± 20%

⚠ The parameters specified are not likely changes due to time.

General Characteristics

Characteristics	Specifications
Voltage	90-240 V~
Power Input	50 VA
Operation Mode	Continuous
Frequency Power	50/60 Hz
Level of protection to the water and solid objects penetration	IP20
Fuse	Nominal Current: 2 A
	Type: T
	Voltage: 250 V~
	Breaking Capacity: 35 A or L
Size	19 cm (depth) x 09 cm (width) x 10 cm (height)
Weight	0,700 Kg
Fiber Diameter	600 µm

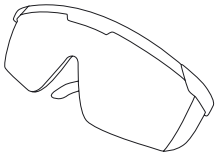
Type of Current	Alternating Current
Software version	2.1
Applied Part	Not Applicable
Protection against electric shock	Class I

SAFETY - IMPORTANT CAUTION

⚠ If any component present damage, it must not be used.

⚠ The use of any part, accessory or material not specified it is the user's entire responsibility.

⚠ The laser light is harmful to the eyes, so the goggles must be used in order to protect them, for everybody in the place, where the session is happening. The DMC provides three goggles along with the Whitening Lase Light Plus. Only the goggles provided by the DMC may be used along with the device. The model of the before mentioned goggle can be seen below:



Goggles
(Green lenses)

⚠ Never look directly to the laser light and more importantly do not direct the light to anybody, unless he/she is under treatment.

⚠ Reflexive surfaces may reflect the laser beam in the eyes direction.

⚠ The usage of flammable or oxidizable anesthetic gases, such as the nitrous oxide (N2O) and oxygen, must be avoided. Some materials, for example cotton, when saturated with oxygen, may inflame by the high temperatures produced. The adhesive solvents and flammable solutions used for cleaning and disinfection must evaporate before the device is used.

⚠ Only trained people can operate the device. The inadequate usage can cause irreversible damages.

⚠ Only the components mentioned in this manual can be used together with the device.

⚠ It is not allowed the usage of the device by unauthorized and not qualified people, aiming at avoiding the incorrect or inappropriate usage.

⚠ The device must not be used with wires and accessories that are not provided by DMC, because it can result in increase of the emissions or decrease of the immunity of the device.

⚠ The device must not be used too close of pilled over other devices. If it is necessary, we recommend that the device is observed in order to check the normal operation in the setup in which it is going to be used.

⚠ The patient must be at least 18 years old to realize the dental whitening.

⚠ The device is not designated to be used in an environment full of oxygen.

⚠ In order to avoid the risk of electrical shock, this device must be connected to only one power supply with grounding for protection.

⚠ The user must not connect the Cable A/C plug in places that are difficult to access, because it can make the device disconnection difficult.

⚠ None modification in this device is allowed.

⚠ The manufacturer does not take any responsibility if the user uses a fuse and an A/C cable different from the ones specified in this manual.

⚠ The user must be exposed to the noise the device does during the maximum period of 8 hours a day.

⚠ The air inputs and outputs must not be obstructed.

⚠ Do not apply any protective film in the handpiece..

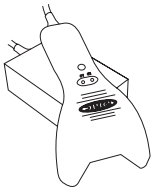
SECURITY ITEMS OF THE DEVICE

The device emites sound signal emission while the handpiece is active.

COMPONENT LIST

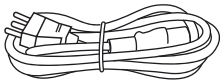
Whitening Lase Light Plus is constituted by the following parts:

PARTS

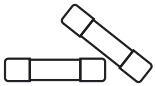


Whitening Lase Light Plus

Handpiece Support

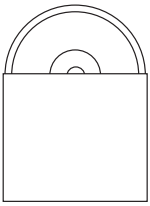


A/C Cable

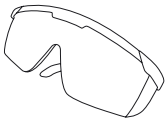


02 Fuses

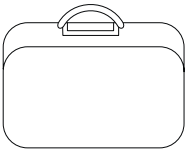
ACCESSORIES



Electronic Media



03 Protection goggles



Transportation Briefcase

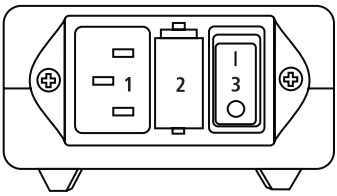
User's Manual and Warranty

If the acquisition of any accessory is necessary, it must be bought at DMC Equipment through the following codes:

- A/C Cable: 010130037 (Manufacturer: STO/Model: Cabo PP 3 x 0,75mm2);
- Goggles: 050020001(Manufacturer: Piramex/Model: ESB460SF);
- Handpiece Support: 110010418 (Manufacturer: DMC/Model 110010418).

⚠ All the accessories and parts described above are for exclusive use in the Whitening Lase Light Plus device.

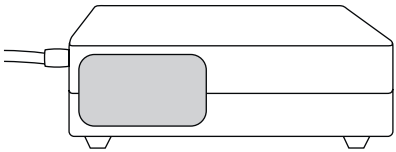
COMMAND BOX PARAMETERS

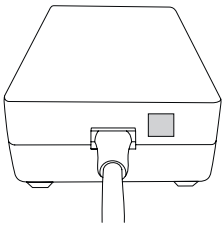


(1) Cable A/C connector: Place where the cable A/C must be connected;
(2) Fuseholder: Place where the device fuses are inserted;
(3) On/Off Switch: Turns on and off the command box;

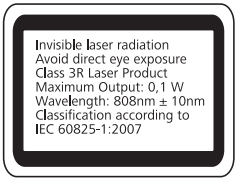
WARNING LASERS

Warnings in the Command Box



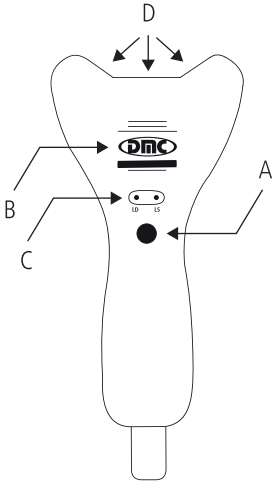


The label below illustrates the laser radiation exposition.



The label below illustrates the laser radiation warning.

HANDPIECE



(A) Activation Button

- **Quick activation:** turn the device on/off
- **Continually press:** alternates between the laser option enabled and disabled.

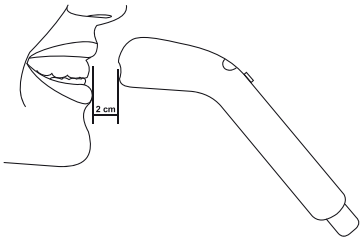
(B) Handpiece fan

(C) LD and LS Leds

LEDs		Equipment Situation
LD	LS	
Led on with continuous emission	Led off	Equipment on in readiness, with infrared lasers disabled.
Led on with intermittent emission	Led off	Handpiece activated with blue or violet LEDs in operation and infrared lasers disabled.
Led on with continuous emission	Led on with continuous emission	Equipment on in readiness, with infrared lasers enabled.
Led on with intermittent emission	Led on with intermittent emission	Handpiece activated with blue or violet LEDs and infrared lasers in operation.

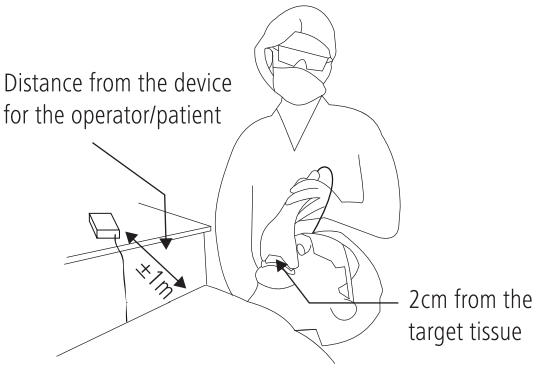
(D) Laser aperture localization (Handpiece LEDs and lasers)
This handpiece has three infrared lasers and six blue or violet LEDs. When it is not being used it is important to keep it in its holder in order to not get damaged.

How to apply the handpiece can be seen below.



PATIENT / OPERATOR POSITION

Below it follows the image with the patient / Whitening Lase Light Plus device operator position.



DESINFECTION

Command box/Handpiece

• The device must be disconnected from the power supply before cleaning, in order to avoid the user exposition to electrical shock;
• The command box must not be washed, it will imply in warranty loss;
• The cleaning consists of using a soft cloth moistened with alcohol 70%.

⚠ Do not allow liquids to drain into the command box, because it will damage it.

⚠ The device can be cleaned/disinfected multiple times, with no damage.

INSTALL

• Fix the support of the handpiece in the appropriate place (clean, flat surface near the point of use);
• Position the dental whitening handpiece in the handpiece support, while not being used;
• Connect the A/C in the command box of the equipment;
• Then insert the A/C cable in the mains.

BEFORE USAGE INSPECTION

Check if all the items mentioned in the INSTALL are connected.

SEQUENCE OF OPERATION

• With the A/C cable inserted into the mains, according to item "Install", activate on/off switch, located on the command box;
• Direct the handpiece to the target tissue, as item "patient /operator position";
• Follow the instructions in the section "How to Use" for activation of handpiece.

USE METHOD

Selection of Laser in Teeth Whitening

To enable or disable emitting lasers with handpiece switched off, the user must hold the button until the "LS" indicator of handpiece is off (disabled) or until it turns on (enabled)

Handpiece Activation

To activate/deactivate the handpiece, just quickly press the power button. Whitening Lase Light Plus is configured for one minute cycles. The emission of beeps and display of LEDs turned on with intermittent emission indicate that the handpiece is activated.

Important Remarks

⚠ If the user wishes to stop the laser emission and LEDs at any time of the application, simply press the button on the handpiece.

⚠ Caution - Use of controls or adjustments or execution of other procedures not specified herein may result in hazardous radiation exposure.

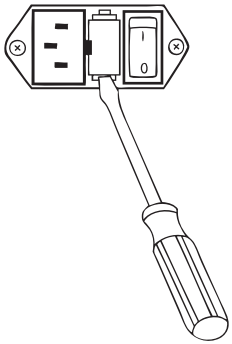
FINALIZATION PROCEDURE

In order to turn off the device, the user must use the On/Off switch located at the command box.

ISOLATION FROM THE SUPPLY MAINS

In case of emergency or for maintenance purposes, the A/C Cable must be disconnected from supply mains, by removing it from the sockets.

FUSE VERIFICATION AND CHANGE PROCEDURE



- Disconnect the A/C cable from the supply mains and from the device;
- By using a screwdriver, undock both edges of the fuse holder lid (see picture below), until it is possible to remove it with the hands;
- Remove each one of the fuses and check if they are burnt – observe if the fuse is dark of with the thread broken;
- If necessary, replace the fuse using a spare fuse provided or another from the same value and features (see the item "SPECIFICATIONS");
- Push the fuse holder with the hands until it locks.

PREVENTIVE MAINTENANCE

The device must be calibrated at least every two years by the manufacturer. If this maintenance is not performed, the manufacturer does not take any responsibility for its safety.

All the assistance services, such as changes, repairs, calibration, etc. can only be performed by the manufacturer. The circuit schemas, components lists, descriptions, instructions for calibration and measurement are not available for people who are not qualified by the manufacturer.

If the maintenance or any other kind of assistance service if performed by unauthorized personnel, the manufacturer do not take any responsibility for the safety of the device functioning.

In order to assure the safe usage of the product, the user must inspect the integrity of the A/C cable, command box and the handpiece in a daily basis, that is, check if this parts are not broken, torn, dirty, etc.

⚠ Never open the command box or the handpiece. At any problem contact the technical assistance of the DMC Equipment.

STORAGE AND TRANSPORTATION

- Store the device away from dust, solar direct exposure, near chemical products and cleaning agents;
- The device must be stored, transported and used in the following environmental conditions:
  Temperature: from +10oC to +40oC;
  Humidity: from 30% to 75%;
  Atmospheric Pressure: from 700hPa to 1060hPa.

⚠ Avoid the device falling.

⚠ Keep the device in a safe place, avoiding hits and vibrations.

PROBLEMS AND POSSIBLE SOLUTIONS

Error	Error Indication	Solutions/Causes Possible
The equipment does not turn on	With on/off switch on "I" (on), no indicator (LD or LS) lights up.	- Check whether the A/C cable is well connected; - Check, with the A/C cable unplugged from the grid, if the fuse is blown, as item "PROCEDURE FOR CHANGE AND CHECKING OF FUSE"; - Check if the outlet is working properly; - Activate the technical assistance of DMC Equipamentos.
Excessive heating of handpiece	Interruption of operation and audible alarm with flashing hand piece switched off	- Clear the air outlet of the handpiece; - Check if the micro fan is locked; - Restart the equipment; - Activate the technical assistance of DMC Equipamentos.
Uncalibrated emissions	Interruption of operation and audible alarm with flashing handpiece switched off	- Restart the equipment; - Activate the technical assistance of DMC Equipamentos.

DISCARDING

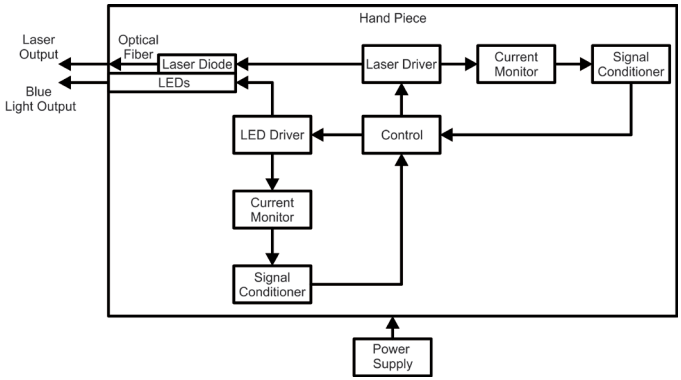
After the product and its accessories life has expired, it can cause environmental harm or can be used incorrectly. In order to minimize these risks, the client must discard the device according to what the local legislation determines.

BIOCOMPATIBILITY

The equipment has no applied part. Therefore, this topic is not applicable.

LASER / LEDS SUPPLY SYSTEM

The dental whitening handpiece is composed by three infrared diode lasers and six blue or violet LEDs. For the lasers the light is conduced to the edge of the handpiece by optical fiber, not replaceable. The blue or violet light is transmitted directly through the LEDs. The optical power emitted is controlled through the electrical current that passes through the diodes and through the LEDs.



CALCULATION OF BEAM DIVERGENCE

Standard: 60825-1:2007
The beam divergence is 0,45 rad ± 0,03 rad.

ELECTROMAGNETIC SAFETY STANDARD OF THE DEVICE

Below there are tables that represent the adjustment to the regulation of electromagnetic immunity and emission.

Guidelines and manufacturer statement – Electromagnetic emission – for all the device and System [IEC 60601-1-2 / 2007 – subcl. 6.8.3.201 a) 3)]		
The Whitening Lase Light Plus is designated for the usage in electromagnetic environment specified below. The client or user of the Whitening Lase Light Plus must assure that he/she is using it in such environment.		
Immunity Trial	**Accordance**	**Electromagnetic Environment - Guideline**
RF Emissions ABNT NBR IEC CISPR 11	Group 1 According	Whitening Lase Light Plus uses RF energy only for its internal functions. Thus, its RF emissions are very low which is not likely that cause any interference in the electronic devices nearby.
RF Emissions ABNT NBR CISPR 11	Class "A"	Whitening Lase Light Plus is convenient for using in all the places that are not designated to domestic use or that are not directly connected to a public power supply of low voltage that powers buildings used for the domestic matter.
Harmonic Emissions 61000-3-2	Not applicable	
Emissions due to voltage floating/scintillation IEC 61000-3-3	Not applicable	

Table 1: Accordance information to the electromagnetic emission requirements based in the table 201 – 60601-1-2, 2007

Guidelines and manufacturer statement – Electromagnetic Immunity – for all Whitening Lase Light Plus [IEC 60601-1-2 / 2007 – subcl. 6.8.3.201 a) 6)]			
The Whitening Lase Light Plus is designated for the usage in electromagnetic environment specified below. The client or user of the Whitening Lase Light Plus must assure that he/she is using it in such environment.			
Immunity Trial	**Level of the IEC60601 trial**	**Level of Accordance**	**Electromagnetic Environment – Guideline**
Electrostatics discharge (ESD) IEC 61000-4-2	± 6 kV per contact ± 8 kV through the air	According	Floors must be made of wood, concrete or ceramic. If the floors are covered with synthetic material, the relative humidity must be at least 30%.
Fast electric transitory/ pulse train ("Burst") IEC 610004-4	± 2 kV in the power lines ± 1 kV in the input/output lines	According	Quality of the energy must be the one from a hospital environment or typical commerce.
Outbreaks IEC 61000-4-5	± 2 kV line (s) to ground ± 1 kV line (s) to line	According	Quality of the energy must be the one from a hospital environment or typical commerce.
Voltage drops, short interruptions and voltage variations in the input supply line IEC 61000-4-11	<5% Ut (>95% of voltage drop in Ut) per 0,5 cycles. 40% Ut (60% of voltage drops in Ut) per 5 cycles 70% Ut (30% Of voltage drops in Ut) per 25 cycles. <5% Ut (>95% of voltage drops in Ut) per 5 seconds	According	Quality of the energy must be the one from a hospital environment or typical commerce. If the user of the Whitening Lase Light Plus demands continuous operation during the energy interruption, It is recommended that the Whitening Lase Light Plus is supplied by a uninterruptable power supply or a battery
Magnetic field in the supply frequency (50/60Hz) IEC 61000-4-8	3 A/m	According	Magnetic fields in the supply frequency must be in specific levels of a typical place in a hospital environment or typical commerce.
NOTE: Ut is the supply voltage c. a. before the application of the trial level.			

Table 2: Accordance Information to the electromagnetic immunity requirements based on the table 202 – 60601-1-2, 2007

Guidelines and manufacturer statement – Electromagnetic Immunity – Device that is not from LIFE SUPPORT - [IEC 60601-1-2 / 2007 – subcl. 6.8]			
The Whitening Lase Light Plus is designated for the usage in electromagnetic environment specified below. The client or user of the Whitening Lase Light Plus must assure that he/she is using it in such environment.			
Immunity Trial	**Level of the IEC 60601**	**Level of accordance**	**Electromagnetic Environment - Guideline**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz up to 80 MHz	3 V	Portable and mobile RF communi-cation devices should not be used nearby any part of the Whitening Lase Light Plus, including cables, with separation shorter than the recommended, calculates from the equation applicable to the trans-mitter frequency. Separation distance recommended D = 10,10 m D = 10,10 m (80 MHz up to 800 MHz) D = 20,20 m (800 MHz up to 2,5 GHz) Where P is the maximum output nominal power of the transmitter in watts (W), according to the manufacturer of the transmitter, and D Is the recommended sepa-ration distance in meters (m). It is recommended that the intensi-ty of the field establi-shed by the RF transmitter, as determined by an electro-magnetic inspection at the locala, is smaller than the ac--cordance level in each frequency rangeb. Interference may happen around the device marked with the follow-ing symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz up to 2,5 GHz	3 V/m	
NOTE 1 – in 80 MHz and 800 MHz, applies to the higher frequency range NOTE 2 – These guidelines cannot be applied in all the situations. The electromagnetic propagation is affected by the structure absorption and reflection, objects and people. a The intensities of the field established by the fixed transmitters, such as radio stations base, telephone (cell Phone/ wireless) and mobile terrestrial radios, amateur radio, radio transmission AM and FM and TV transmitters do cannot be accurately foreseen theoretically. In order to evaluate the electromagnetic environment due to the fixed RF transmitters, it is recommended an electromagnetic inspection at the local. If the measurement of the field intensity at the local in which Whitening Lase Light Plus is used exceeds the accordance level used above, the Whitening Lase Light Plus should be obser-ved to check if the operation is normal. If an abnormal development if observed, additional procedures may be necessary, such as a reorienting or rearranging of the Whitening Lase Light Plus. b Over the frequency range of 150 kHz up to 80 MHz, the field intensity should be lower than 3 V/m			

Table 3: Accordance information to the electromagnetic immunity requirements for devices which aims at LIFE-SUPPORT based on the Table 204 – 60601-1-2, 2007

Distance and minimum separation recommended between the RF portable and mobile communication devices and the Whitening Lase Light Plus.			
The Whitening Lase Light Plus is designated for using at the electromagnetic environment in which radiated RF disturbances are controlled. The client or user of Whitening Lase II may help to prevent the electromagnetic interference keeping the minimum distance between the portable or mobile RF communication (transmitters) and the Whitening Lase Light Plus, as recommended below, according to the maximum output power of the communication devices.			
Nominal maximum power of the transmitter (W)	Separation distance according to the transmitter frequency (m)		
	150 kHz up to 80 MHz	80 MHz up to 800MHz	800 MHz up to 2,5 GHz
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,2	1,2	2,3
10	3,7	3,7	7,4
100	12	12	23
For transmitters with an output nominal maximum power not listed above, the separation distance recommended (in meters [m]) can be determined by the equation applicable for the transmitter frequency.			
Note 1: in 80 MHz up to 800 MHz, the separation distance is applied for the highest frequency range. **Note 2: these guidelines cannot be applied in all situations. The electromagnetic propagations are affected by the structure absorption and reflection, objects and people.**			

Table 4: separation distance between the device and the RF emission sources recommendations based on the Table 206 – 60601-1-2, 2007

WARRANTY

A. The devices manufactured and/or commercialized by DMC have a 24 (twenty-four) months warranty, from the date of the purchase, against any manufacturing defect.
B. The warranty covers only manufacturing defects or of material used in the manufacturing of the products. The warranty DO NOT covers shipping expenses.
C. The warranty is automatically cancelled, in case of any electrical or physical abuse happen, if the parts were altered, or if applications different from those the device is developed for happened.
D. In case of repaired devices out of the warranty period, it will only be extended to the replaced parts.
E. The causes of the defects more common come from physical shock applied to the device, in these cases the warranty is cancelled.
F. The DMC does not take any responsibility for personal or material damages from the misusage of the devices they manufacture and/or commercialize, it is the user's responsibility to provide safety procedures in order to avoid such problems.
G. The DMC responsibility concerning to the use of the device and its consequences, limits to the replacement of the amount of the device.
The device will only be under the manufacturer warranty regulations if:
• The assembling, extensions, adjusts, modification or repair operations were performed by people authorized by them;

- The electrical installation of the environment in focus is in accordance with the appropriate requirement;
- The device is used according to the instructions.

SYMBOLS USED


Laser Radiation


Check the user's manual.


Caution!

Protected against solid strange objects of 12,5 mm of diameter and not protected against water drain.

On (with voltage)


Off (without Voltage)


Date of Manufacture


Manufacturer


Alternate Current

Serial Number


Fragile,
handle with care


Indicates the position for transport


Keep away from sunlight


Protect from heat and radioactive sources

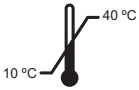

Keep dry


Do not overturn

Maximum Pilling

Humidity Limitation

Authorized Representative in the European Community



Temperature limits

EC REP

MDI Europa GMBH
Langenhagener Straße 71
30855 - Langenhagen
Germany

DMC EQUIPAMENTOS LTDA
Rua Sebastião de Moraes, 831 - Jardim Alvorada
São Carlos/SP - Zip Code 13562-030
CNPJ 02.827.605/0001-86
Tec. Resp. Renaldo Massini Jr. – CREA 0601706815
ANVISA Registry : 80030810015
Technical Name: Laser appliance for odontologic treatment

Technical assistance:
DMC EQUIPAMENTOS LTDA
Phone: (16) 2107-2323 - Fax (16) 2107-2320

21-MAN-132 Review: 05 Review Date: 01/04/2013