



अखिल भारतीय आयुर्विज्ञान संस्थान, गोरखपुर

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, GORAKHPUR

कुनराघाट, गोरखपुर, उत्तर प्रदेश – 273008

Kunraghat, Gorakhpur, Uttar Pradesh 273008

(स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार द्वारा स्थापित एक स्वायत्त निकाय)

(An autonomous organization under the Ministry of Health & Family Welfare, Govt. of India)

Ref. No. AIIMS/GKP/Admin/2021-23/594

Date: 07/05/2022

Subject: Purchase of Surgical Workstations for department of Surgery, AIIMS Gorakhpur on proprietary basis- Inviting comments thereon.

As per decision taken / approved by the Competent Authority of AIIMS for purchase of subject cited equipment from M/S ERBE Elektromeizin GmbH on Proprietary Certificate. The Proposal submitted by **M/s PCL Healthcare**, having address : 2, Maqbara Road, Punn Building, Ground floor, Hazrat ganj, Lucknow under proprietary article certificate, certified by user is attached.

The above mentioned document are being uploaded for open information to submit their objections comments, if any firm any manufacturer regarding proprietary nature of the equipment/ accessories/ item within 15 days from the date of issue/ uploading of the notification.

The comment should be received by office of administrative officer, Medical College at AIIMS, Gorakhpur on or before 22 May 2022 up to 17:00, Hrs. failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

S/D

**Administrative Officer
AIIMS Gorakhpur**

Enclosure: Related Documents enclosed

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Technical Specification for Combined High-End RF, Argon Plasma and Water Jet Surgical WorkStation with Automatic Surgical Smoke Evacuation System.

An integrated RF, with Argon and Kinetic energy surgical platform which can dissect, coagulate and seal the tissues during open and laparoscopic surgeries. System should comprise of below Type of Module Energies.

RF Energy Platform -Electro surgery unit with Thermo fusion (Vessel Sealing)

- The Electro surgical generator should be a 400watt touch screen display with 15 digital signal processors.
- Unit should facilitate functions of monopolar, bipolar & vessel sealer with in-built regulated power supply adapter for bipolar resection.
- Unit should have a Step guide suggesting appropriate setting configurations for every instrument and application.
- The system should make 25 million measurements / sec for better tissue effect and should measure tissue impedance through power peak system.
- System should have wifi compatibility for future OR integration.
- Unit should be plug & play with 5 or more universal multi-functional sockets to accommodate any instrument.
- System should have remode function to allow user to access 6 sub programmes directly from the sterile field.
- Unit should have high cut mode for monopolar modalities
- Each socket should support the Auto start function for bipolar instruments.
- Unit should have the facility for socket exchange.
- Unit should have Soft Coagulation mode with quick start function for any open or laparoscopic application
- Unit should have Precise Sect mode for optimized dissection in open or laparoscopic cases
- The generator should work on a supply voltage of 100 – 120 VAC & 220 – 240 VAC
- Power consumption at Max HF power should be 550 watts with max pulse power consumption of 1600 watts.
- Should have a special Coagulation mode called “Thermoseal” with auto start function for highly vascularized tissue bundles and vessels upto 7mm diameter and min. burst 360mmHg burst pressure.
- Unit should have an Auto Cut bipolar mode to facilitate bipolar cutting instruments.
- Supply frequency should be in the range of 50 -60 Hz.
- Unit should have the facility to store 1800 programmes or applications.
- Unit should have the facility to show the active instruments on the screen display.
- The generator should have an inbuilt feature of accessory assignment.
- The unit should have high cut bipolar to facilitate bipolar resectoscopes.
- The generator should be supplied with Argon plasma coagulation unit having forced APC, pulsed APC and precise APC modes.
- The generator should be supplied with Hydrojet to facilitate use of unique hybrid technology instruments for All Surgical Modalities.
- Unit must be compatible& Supplied with Intelligent smoke evacuation module and suction module. from Same OEM
- Unit should support Nussy as a neutral electrode.

Argon Plasma Coagulation

For management of bleeding and devitalization of tissue abnormalities achieved by optimal coordination with RF generator

- The Argon Plasma Coagulation system should have automatic parameters setting for various types of instruments and automatic depth controlled plasma regulation.

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- Should have three different APC modes suitable for different indications
 - Precise APC – adjustment made using the effect settings
 - Pulsed APC – adjustment made using the parameter power settings
 - Forced APC – adjustment made using the parameter power settings
 - Should have Adjustable argon flow rate from 0.1L/min to 8L/ min in steps of 0.1 L /min with automatic regulation of selected flow rate.
 - Should have the facility to use Argon plasma coagulation and monopolar coagulation simultaneously
 - Should have automatic monitoring of flow rate and Argon supply and auto purge facility. It should have the facility to connect with central gas supply.
 - Should give visual display of argon gas bottle content and should give Acoustic alarm when bottle content reaches a minimum.
 - Should have facility for activation of unit by foot pedal of the Electro Surgical unit.
 - Should have facility to use in double balloon endoscopy procedures.
 - Should have facility for Argon supported cutting and coagulation.

Water Jet Tissue Dissection System

For management of separating the different tissue types with their varying elasticity and firmness with the help of adjusted water pressure based on the kinetic energy principle.

- Should have pressure range:1–80 bars & Volume flow:1–65ml/min. It should indicate delivered fluid vol.
- Should adapt any sterile saline solution bag (disposable) as separation medium.
- Should be integrated with Electro surgical workstation with other accessories and facility to connect Monopolar coagulation with the applicator
- Should have facility to individually configure programs for different surgeries.
- Water jet activation should be via footswitch and Remote facility for switching between two different user settings.
- Should have facility for various applicators to be used in Laparoscopy, flexible endoscopy and open surgeries.

Automatic Smoke Evacuation Unit

- The smoke plume evacuation system should be microprocessor controlled, US-FDA and / or European Certificate marked in accordance with the medical devices directive (93/42/EEC) & Electro Surgical Unit should comply with the requirement of the medical device directive of class I equipment and electromagnetic compatibility.
- The smoke plume evacuation system should be compatible with already installed VIO Surgical Workstation & Electrosurgical Units and should be fitted into same station trolley for smooth functioning and ergonomics.
- The smoke plume evacuation system should be able to extract and filter smoke and aerosol- laden air during surgical procedures & should be also able to filter COVID -19 like viruses and other microorganism present in surgical smoke generated during the procedure.
- The system should have a functional 5.7 inches touch screen display for better visibility& ease of control & display should be able to show settings, operating modes, filter run-time and information messages for the user.
- The System should have Bi-Turbo technology for effective filtration, should have ULPA-15 filter (5 stage filter protection) and active carbon filters & should also have ability to remove 99.9995% of all 0.1µm particles.
- The system filter should have maximum output of 730 l/min & have the ability to give a notification when volume flow of more than 300l/min is reached.

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- The system should have ability to be used along with any electrosurgical unit, Laser and ultrasound devices & system should have automatic activation feature, no need of any additional footswitch for activation during monopolar electrosurgical applications.
- The system should display error if filter is not inserted to prevent damage & system should be able to used in vertical as well as horizontal way as per user needs.
- The system should have the ability to be fixed on the ceiling units (OT pendants) & should have the ability to be used with 2 instruments at the same time during any Surgical Procedures.
- The system should be able to used in open as well as lap surgical procedures with All required Accessories from same OEM only & system noise development at 100% evacuation should be ≤ 59 dB as must have sound insulation cladding, integrated ducts and airborne sound absorbers for noise insulations.
- The user should be able to set critical features like - suction efficiency, standby suction efficiency as well as standby suction time in both lap and open surgery modes & should have footswitch activation facility for laser and ultrasonic uses during procedure.
- The system should be provided with self-sealing water trap to protect the main filter cartridge from liquids & weight of system should be < 10 kgs.
- Service life of the unit filter should be for:
 - **OPEN SURGERIES**
 - 40 hrs at 30% evacuation
 - 32 hrs at 60% evacuation
 - 25 hrs at 100% evacuation
 - **LAPAROSCOPY SURGERIES**
 - 80 hrs at 30% evacuation
 - 60 hrs at 60% evacuation
 - 25 hrs at 100% evacuations
- The smoke evacuator unit should have an interface to connect it to the Electro Surgery system and should also be used as a "stand alone" unit.
- The unit should have provision to be activated via the interface to the Electrosurgery unit, and the time and type of activation can be selected and stored for every output socket and for every cutting or coagulation mode of each program of the Electrosurgery unit.
- The unit should additionally be activated manually using the START / STOP button or the footswitch. Deactivation should be controlled via the interface or by programming an after-run time.
- For safety reasons, an automatic function check of the unit and of the activation components connected to the unit should be performed after the mains switch has been switched on.
- A System display should indicate the filter level.
- The smoke evacuator unit should be supplied with essential accessory Filter Cartridge.
- The smoke evacuator unit should be supplied with essential accessories of same O.E.M
- One pedal foot switch AP & IP 100% water proof endorsed by IPX8 certification of same O.E.M.

Following accessories to be supplied with the surgical workstation. From Same OEM only.

- Reusable hand pencil with Coated Monopolar Electrodes – 05 Nos / If Disposable – 250 Nos .
- Reusable Thermo fusion hand instrument for open & Lap surgeries (for vasculatures up to 7mm) – 02 Nos Each / If Disposable – 05 Nos Each.
- 5mm bowel shaped sealing and cutting hand instrument with maximum of 1.1 mm thermal spread – 02 Nos Each .(Open & Lap Surgeries)
- 100 % Washable – IPX8 Footswitch with facility for swapping between programs – 2Nos.

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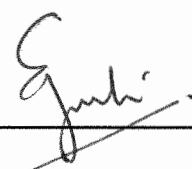
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- **Reusable** Bipolar Lap Scissor for Lap surgery with cable – **02 Nos / If Disposable – 25 Nos**
- **Reusable** Laparoscopic Cable & Attachments for Minimal Invasive Instruments- **02 Nos / If Disposable - 100 Nos**

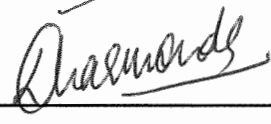
Following Accessories from the same OEM only should be supplied as Standard Accessories Along with Automatic Smoke Evacuator unit.

- Main filter cartridge IES 3- **01 Qty**
- Automatic Activation Device IES 3- **01 Qty**
- Pre-filter for smoke evacuation- **05 Qty**
- Smoke evacuation pencil, single-use, short with coated spatula electrode, connecting cable 3 m- **05- Qty**
- Evacuation tubing, ø 22 mm, length 2.1 m (reusable)- **01 Qty**
- Evacuation tube with optimized streaming- **01 Qty**
- Evacuation funnel connection, ø 22 mm- **01 Qty**
- LAP tubing set IES 3 with trumpet valve 3m- **05 Qty**
- One-pedal foot switch for IES 2, AP & IP X8 equipment; with connecting cable 5 m, with connecting plug 7 poles - **01 Qty**

Dr. Gaurav Gupta
In-charge Dept. of Gen. Surgery & DMS (OT)

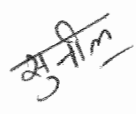


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Dr. Sunil Kumar Gupta
Associate Professor
Dept. of Dermatology



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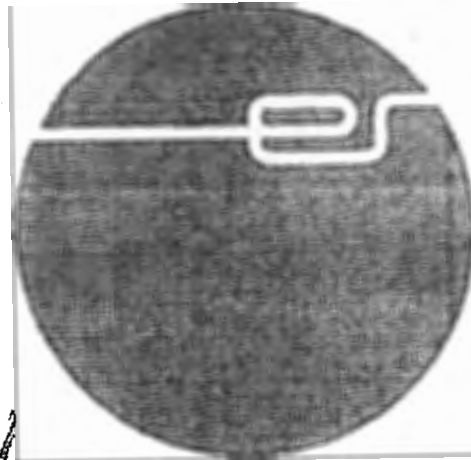


Proprietary Certificate

To whom it may concern

ERBEJET® 2

This is to certify that the ERBEJET 2 is a proprietary product, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and this product is not manufactured elsewhere.



Date 2017-02-15

Andreas Retzlaff, Director Regulatory Affairs

Proprietary Certificate

Erbe Elektromedizin GmbH Waldhoernlestrasse 17 72072 Tuebingen Germany

For PCL HEALTH CARE PVT. LTD.

DIRECTOR

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VALID PATENTS FOR THE ERBEJET 2

ERBE Elektromedizin GmbH hereby declares that the following patents are registered for the device 'ERBEJET 2':

Waterjet surgical device with single-use pump cartridge

Country	Patent number	Description
Germany	DE102004015738A	Medical pump
Japan	JP2005504886A	Medical device
China	CN10081130A	Medical pump
Australia	AU2005240578B	Medical pump

Filling function for waterjet surgical device

Germany	DE102004015738A	Waterjet surgical device and process for operating said device
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Pump cartridge for WJ with controllable drive

Country	Patent number	Description
Germany	DE102004015738A	Medical pump for a waterjet used in surgery, comprises a drive unit for opening and closing nozzle for spraying water
USA	US7055007	Surgical device using water jet and a method for operating said device
Japan	JP2005505635A	Surgical device using a water jet and a method for operating said device
China	CN100810184881A	Surgical device using water jet and method for operating said device
India	IN248194A1	Medical pump
Australia	AU2005255552B2	Medical pump

Transport device for sterile media

	EP1670371B2	Transport device for sterile media
USA	US8083493B2	Transport device for sterile media
Japan	JP2007507261A	Aseptic medium transport device
China	CN100548229C	Transport device for sterile media
India	IN1446CHENP2006A	Transport device for sterile media
Australia	AU2004279670B2	Transport device for sterile media

Tuebingen, 12 September 2012

J.A. G. G. G.
Marketing Director, GERMANY

Website: www.erbe.com | erbe@erbe.com | www.erbe.com

ERBE



For PCL HEALTH CARE PVT.LTD.
[Signature]
DIRECTOR

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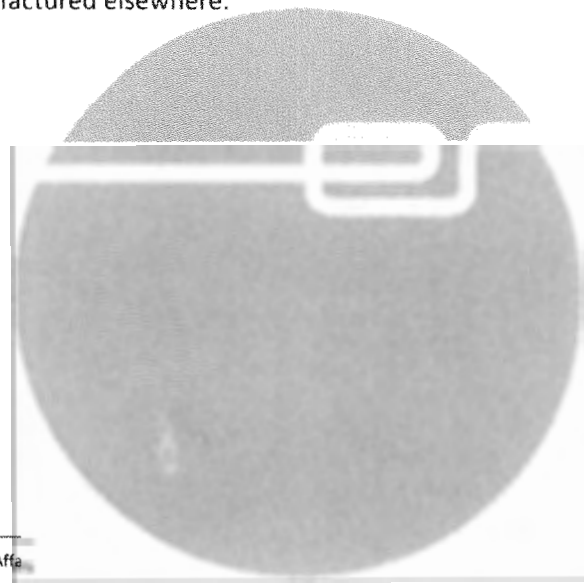



Proprietary Certificate

To whom it may concern

Erbe VIO[®] 3 and APC 3

This is to certify that the Erbe VIO[®] 3 with attached Argon Plasma Coagulation system (APC 3), that provides facility to change between programs by a ReMode button, specially designed Cut and Coag modes for different medical and surgical disciplines, like softCOAG[®], preciseSECT and dryCUT[®] and also three different variations in Argon Plasma outputs namely FORCED APC, PULSED APC[®] and PRECISE APC[®] are proprietary products, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and these products are not manufactured elsewhere.




Axel Retzlaff, Manager Regulatory Affa

Date 2019-06-12

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DIRECTOR

Proprietary Certificate

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power your performance.

Proprietary Certificate

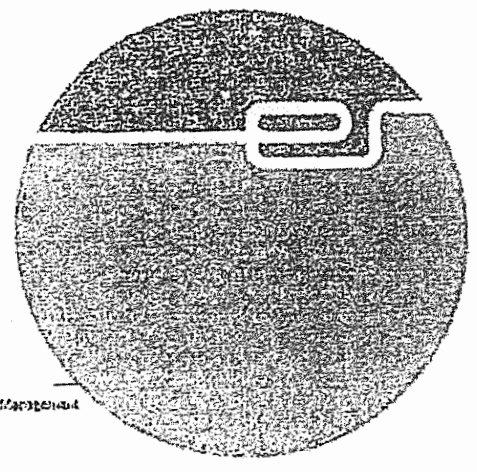
To whom it may concern

Erbe IES 3

This is to certify that the smoke evacuation system IES 3 with 5 stage main filter cartridge, that contains a ULPA-15 filter that removes 99.9995% of all particles from 100 nm and that can be used for open surgical and laparoscopic applications, is a proprietary product, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and is not manufactured elsewhere.

This system is compatible with all models of the VIC® range proprietary to Erbe Elektromedizin GmbH.

Michael Beck, Director Business Management



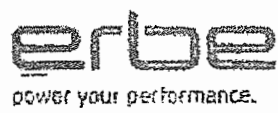
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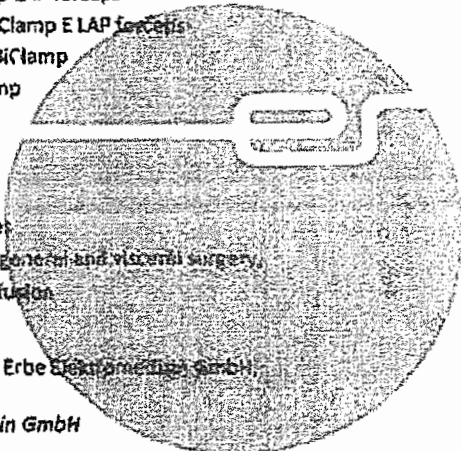
BiClamp®

This is to certify that the following products :

- 20195-134...-137,-228; 21195-134...-137,-228 BiClamp LAP forceps
- 20195-229,-230,-246...-249; 21195-229,-246...-249 BiClamp E LAP forceps
- 20195-200,-202,-203,-213,-221,-227,-230,-280,-299 BiClamp
- 21195-190,-200,-202,-203,-221,-230,-280,-299 BiClamp

are specially designed to enable

- for open surgery and laparoscopic procedures
- vessel sealing in urology, gynecology, and in general and visceral surgery,
- BiClamp and thermoSEAL modes for thermofusion



These are proprietary products, marketed exclusively by Erbe Elektromedizin GmbH,
 Waldhoerlestrasse 17, 72072 Tuebingen, Germany.
 BiClamp® is a registered trademark of Erbe Elektromedizin GmbH

Michael Bueck, Director Business Management

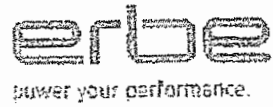
Proprietary Certificate

Erbe Elektromedizin GmbH Waldhoerlestrasse 17 72072 Tuebingen Germany

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Proprietary Certificate

To whom it may concern

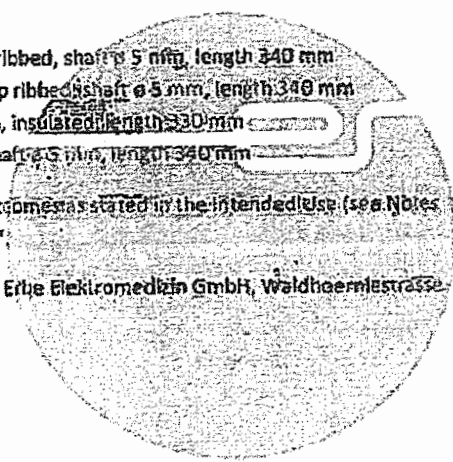
Bipolar Instruments

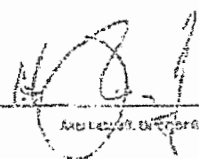
This is to certify that the following products :

- 20195-132 Bipolar LAP forceps, Maryland, deep ribbed, shaft ø 5 mm, length 340 mm
- 20195-133 Bipolar LAP forceps, fenestrated, deep ribbed, shaft ø 5 mm, length 340 mm
- 20195-081 Bipolar fixation forceps, shaft ø 5 mm, insulated length 330 mm
- 20195-226 Bipolar LAP scissors, Metzenbaum, shaft ø 5 mm, length 340 mm

are specially designed to achieve the desired surgical outcomes as stated in the intended use (see Notes on Use of each product) in different surgical procedures"

These are proprietary products, marketed exclusively by Erbe Elektromedizin GmbH, Waldhaerlestrasse 17, 72072 Tuebingen, Germany.



 20.11.2015
 Axel Leuchter, Director Regulatory Affairs

Proprietary Certificate

Erbe Elektromedizin GmbH, Waldhaerlestrasse 17, 72072 Tuebingen, Germany

For PCL HEALTH CARE PVT. LTD.


DIRECTOR

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Proprietary Certificate

To whom it may concern

Erbe Bipolar PREMIUM Forceps

This is to certify that the listed Bipolar PREMIUM Forceps are proprietary products, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and these product are not manufactured elsewhere.

Article No.	Catalogue Description
20195-501	Bipolar forceps PREMIUM, straight, tip 0.2 mm, pointed, length 120 mm
20195-502	Bipolar forceps PREMIUM, straight, tip 0.4 mm, very fine, length 120 mm
20195-503	Bipolar forceps PREMIUM, straight, tip 0.7 mm, fine, length 120 mm
20195-504	Bipolar forceps PREMIUM, straight, tip 0.7 mm, fine, angled, length 120 mm
20195-505	Bipolar forceps PREMIUM, straight, tip 0.2 mm, pointed, length 185 mm
20195-506	Bipolar forceps PREMIUM, straight, tip 0.4 mm, very fine, length 185 mm
20195-507	Bipolar forceps PREMIUM, straight, tip 0.7 mm, fine, length 185 mm
20195-508	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, length 185 mm
20195-509	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, angled, length 185 mm
20195-510	Bipolar forceps PREMIUM, straight, tip 0.2 mm, pointed, length 200 mm
20195-511	Bipolar forceps PREMIUM, straight, tip 0.4 mm, very fine, length 200 mm
20195-512	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, length 200 mm
20195-513	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, angled, length 200 mm
20195-514	Bipolar forceps PREMIUM, straight, tip 2 mm, blunt, angled, length 200 mm
20195-515	Bipolar forceps PREMIUM, straight, tip 2 mm, blunt, length 230 mm
20195-516	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, angled, length 260 mm
20195-517	Bipolar forceps PREMIUM, straight, tip 2 mm, angled, length 260 mm
20195-518	Bipolar forceps PREMIUM, straight, tip 2 mm, blunt, length 280 mm e.g. for urology
20195-531	Bipolar forceps PREMIUM, bayonet, tip 0.2 mm, pointed, length 155 mm
20195-532	Bipolar forceps PREMIUM, bayonet, tip 0.4 mm, very fine, length 155 mm
20195-533	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 155 mm
20195-534	Bipolar forceps PREMIUM, bayonet, tip 0.2 mm, pointed, length 170 mm
20195-535	Bipolar forceps PREMIUM, bayonet, tip 1 mm, blunt, length 170 mm
20195-536	Bipolar forceps PREMIUM, bayonet, tip 0.4 mm, very fine, length 200 mm
20195-537	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 200 mm
20195-538	Bipolar forceps PREMIUM, bayonet, tip 1 mm, blunt, length 200 mm
20195-539	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 200 mm
20195-540	Bipolar forceps PREMIUM, bayonet, tip 2 mm, blunt, length 200 mm
20195-541	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 200 mm angled downwards
20195-542	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 200 mm angled upwards

For PCL HEALTH CARE (VT) LTD.

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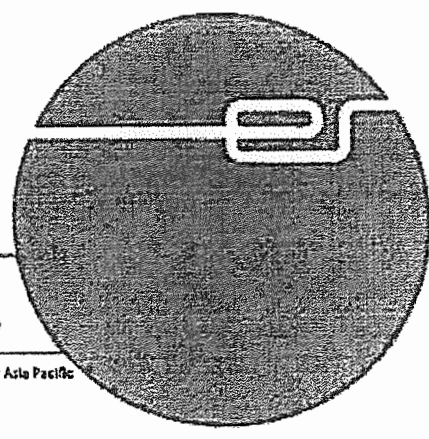
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20195-543	Bipolar forceps PREMIUM, bayonet, tip 0.2 mm, pointed, length 230 mm
20195-544	Bipolar forceps PREMIUM, bayonet, tip 0.4 mm, very fine, length 230 mm
20195-545	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 230 mm
20195-546	Bipolar forceps PREMIUM, bayonet, tip 1 mm, blunt, length 230 mm
20195-547	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 230 mm
20195-548	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 230 mm angled upwards
20195-549	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 230 mm angled upwards
20195-550	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 230 mm angled downwards
20195-551	Bipolar forceps PREMIUM, bayonet, tip 0.2 mm, pointed, length 250 mm
20195-552	Bipolar forceps PREMIUM, bayonet, tip 0.4 mm, very fine, length 250 mm
20195-553	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 250 mm
20195-554	Bipolar forceps PREMIUM, bayonet, tip 1 mm, blunt, length 250 mm
20195-555	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 250 mm
20195-556	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 250 mm angled upwards
20195-557	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 170 mm
20195-558	Bipolar forceps PREMIUM, bayonet, tip 2 mm, blunt, length 250 mm
20195-559	Bipolar forceps PREMIUM, bayonet, tip 2mm, blunt, length 170 mm
20195-560	Bipolar forceps PREMIUM, bayonet, tip 0.2 mm, pointed, length 200 mm
20195-561	Bipolar forceps PREMIUM, bayonet, tip 2 mm, blunt, length 230 mm

erbe

Erbe Elektromedizin GmbH
 Waldhoernlestrasse 17
 72072 Tübingen, Germany

N. Zierhut



Date 2011-02-18

Natalie Zierhut, Business Manager Asia Pacific

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Baden-Württembergische Bank
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Kreispostamt Tübingen
 IBAN: DE44 1201 0110 0001 0001 00

For PCL HEALTH CARE PVT. LTD.

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 DIRECTOR

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Proprietary Certificate

To whom it may concern

Nessy® Omega

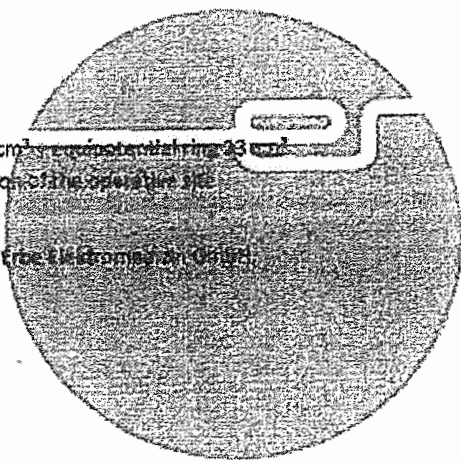
This is to certify that the following products :

- 20193-082 Nessy Omega, split patient plate
- 20193-083 Nessy Omega, split patient plate

are specially designed

- with a split-pad effective contact surface 85 cm² and constant width 43 mm
- and can be applied irrespective of the direction of the operative site

These are proprietary products, marketed exclusively by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany.



April 4 2013

Michael Reiser, Director Business Management

Proprietary Certificate

Erbe Elektromedizin GmbH Waldhoernlestrasse 17 72072 Tuebingen Germany

For PCL HEALTH CARE PVT. LTD.

DIRECTOR