DR. B.R.A.INSTITUTE ROTARY CANCER HOSPITAL
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI -110029.
(STORES SECTION)

Ref. No.- 01/Stores (DR. B.R.A.I.R.C.H.)/LOU/Proprietary/M&E/2014-15/FSC Date

Dated: 30/01/2015

Subject:

Purchase of Combined Generator of Ultrasonic & RF energy for Simultaneous cutting and coagulation for Dept. of Surgical Oncology ( Dr. BRAIRCH, AIIMS , New Delhi) on proprietary basis –reg.

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The Institute is in the process to purchase Combined Generator of Ultasonic & RF energy for Simultaneous cutting and coagulation for Dept. of Surgical Oncology ( Dr. BRAIRCH, AIIMS , New Delhi) from M/s. Johnson & Johnson USA on proprietary basis. The proposal submitted by M/s. Johnson & Johnson USA and PAC certifications are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within issue of 10 days giving reference **01/Stores (DR. B.R.A.I.R.C.H.)/LOU/Proprietary/M&E/2014-15/FSC** The comments should be received by office of Stores Officer ( Dr. B.R.A.I.R.C.H.), Store Section, Room No. 18, G.F. ( Dr. B.R.A.I.R.C.H. Building, AIIMS ) on or before 27.02.2015 upto 12.30 p.m., failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

Stores Officer Dr. B.R.A.I.R.C.H. A.I.I.M.S.

Encl.: Related documents enclosed



: 25930530, 25930890 : 42520000, 25441277 : JOHNSONIAN : 91-11-25430042



BRANCH OFFICE: 9/43, KIRTI NAGAR, NEW DELHI-110015

Date - 02/12/2014

To The HOD, Department of Surgical Oncology, AIIMS, New Delhi.

#### Subject :- Description of GEN11 & accessories

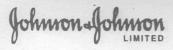
#### Attached documents :-

- 1. GEN11 Proprietary & patent certificate
- 2. Quotation
- 3. Distributor authorization
- 4. Company's proprietary article certificate
- 5. Rate certificate
- 6. Benchmark copy

S.NO.	Code	Product Description
1	GEN11	Combined generator of Ultrasonic & RF energy for simultaneous cutting & coagulation. The system has below mentioned features :-
		<ul> <li>A universal connector to connect Ultrasonic energy and Advanced RF energy instruments.</li> </ul>
		Have automatic instrument recognition.
		System is CE approved.
		<ul> <li>System has touch screen display for fast and setup, operation and on- screen diagnostics.</li> </ul>
		System has a high-resolution display with wide viewing angles.
5,20,0	4.2.2.2	System has the ability for software updates via USB memory stick.
		A single generator that provides Ultrasonic energy and Advanced RF energy technology for soft tissue dissection and vessel sealing
		<ul> <li>System has a potential equalization terminal for compatibility with other medical systems requiring such connections</li> </ul>
		<ul> <li>System confirm to the following international standards EN (IEC) 60601-1</li> <li>EN (IEC) 60601-1-2, EN (IEC) 60601-2-2, EN (IEC) 60601-1-8</li> </ul>
		System provides Class 1 protection against electric shock.
		<ul> <li>System has a single footswitch for operating ultrasonic energy or advanced RF energy instruments.</li> </ul>
		System has the ability to select handswitch or footswitch activation or
		both for Ultrasonic and advanced RF energy instruments and the ability to change selection during use.
		<ul> <li>System has 6 international language options with English language as default.</li> </ul>
		System comes equipped with system diagnostics and
		troubleshooting guide to pin point any problems in the systems.







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- System has onscreen warning display system for generator overheating, generator software upgrade, handpiece errors and instrument errors
- System powers ultrasonic energy instruments with 55.5 KHz frequency and have the ability to power ultrasonic energy instruments in the frequency range of 30-80 KHz in future
- The hand piece for the system comes with an inbuilt transducer.
- System is compatible for open surgery and for laparoscopic surgery.
- System has 5 power settings levels with power level display for ultrasonic energy instruments.
- System powers energy instruments with microprocessor controlled bipolar electrosurgical radiofrequency technology with a quasisinusoidal forced impedance output.
- System is equipped with smart advanced RF energy technology to measure the tissue impedance and control the power delivery.
- System is equipped with advanced RF energy technology that can simultaneously seal and transect vessels up to and including 7mm, large tissue pedicles and vascular bundles.
- System is equipped with advanced RF energy technology that provides temperature controlled energy delivery which should maintain tissue temperature approximately at 100 degree Celsius.
- System has Advanced RF Energy hand instruments with a unique electrode configuration to minimize the lateral thermal spread.
- System has Advanced RF Energy hand instruments with technology to deliver high compression uniformly across seal area.
- System has Advanced RF Energy hand instruments that provide tissue / vessel seal strength to withstand bursting pressure of 7 times the systolic pressure.
- All hand probes for open and lap procedures are able to simultaneously cut and coagulate tissues.
- System is able to power advanced RF energy hand instruments of 5mm shaft diameter for both open & laparoscopic procedures with round tip (5mm tip width) in the following shaft lengths (14cm, 25cm, 35cm & 45cm) and is both hand & foot activated.
- Systems is able to power ultrasonic energy hand instruments of 5mm shaft diameter for both open & laparoscopic procedures.





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2	CRT11	Cart for Combined generator of Ultrasonic & RF energy
3	FSW11	Single footswitch for Combined generator of Ultrasonic & RF energy
4	HGA11	Adaptor for Ultrasonic energy delivery
5	EGA11	Adaptor for RF energy delivery
6	HP054	A connecting cable for Ultrasonic Scalpel (open & laparoscopic) compatible with Ultrasonic generator & Combined generator.
7	NSLG2S14	Hand Activated tissue sealer straight- 5.5 mm diameter, 14 cm long, capable of sealing blood vessels up to 7mm in diameter, Ergonomic handle compatible with Combined Generator of Ultrasonic & RF energy.
8	NSLG2C35A	Hand Activated 5 mm diameter tissue sealer Articulating curved jaw, 35 cm long with a 110 degrees articulating joint (55 degrees each direction) & 360 degrees rotation knob, capable of sealing blood vessels up to 7mm in diameter, articulation wheel to help lock in desired angle of approach, Ergonomic handle compatible with the combined Generator of Ultrasonic & RF energy.
9	HAR36	Hand Activated Curved Coagulating Shear with Adaptive tissue technology & a finer, non-stick coated blade- 5.5 mm diameter, 36cm long, capable of sealing blood vessels up to 5mm in diameter, Ergonomic handle compatible with the combined Generator of Ultrasonic & RF energy
10	FCS9	Hand activated curved taper tip coagulating shears compatible with ultrasonic cutting and coagulation device, 240 degree hand activation buttons, 9 cm length, 16mm curved active blade capable of sealing blood vessels up to 5mm in diameter, with ergonomic symmetrical finger ring grip compatible with Combined generator of Ultrasonic & RF energy
.11	FCS17	Hand activated curved taper tip coagulating shears compatible with ultrasonic cutting and coagulation device,240 degree hand activation buttons,17cm length,16mm curved active blade capable of sealing blood vessels up to 5mm in diameter, with ergonomic symmetrical finger ring grip compatible with Combined generator of Ultrasonic & RF energy.

Yours sincerely

Yogesh Upadhyay District Manager Ethicon Endo-Surgery

Johnson & Johnson Medical India

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BRANCH OFFICE: 9/43; KIRTI NAGAR, NEW DELHI-110015

Date:-15<sup>th</sup> November 2014

### PROPRIETARY ARTICLE CERTIFICATE

## To Whom It May Concern:

This is to certify that the Combined generator of Ultrasonic & Advanced RF Energy, (Product code: **GEN11**) for simultaneous cutting & coagulation of soft tissue with

- A universal connector to connect Ultrasonic energy and Advanced RF energy instruments.
- Automatic instrument recognition.
- A touch screen display for fast and setup, operation and on-screen diagnostics.
- The ability for software updates via USB memory stick.
- A single footswitch for operating ultrasonic energy or advanced RF energy instruments.
- The ability to select hand-switch or footswitch activation or both for Ultrasonic and advanced RF energy instruments.
- Onscreen warning display system for generator overheating, generator software upgrade, handpiece errors and instrument errors.
- The hand piece with an inbuilt transducer.
- 5 power level settings with power level display for ultrasonic energy instruments.
- Advanced RF energy technology that can simultaneously seal and transect vessels up to and including 7mm, large tissue pedicles and vascular bundles.
- Advanced RF Energy hand instruments with a unique electrode configuration to minimize the lateral thermal spread.
- Advanced RF energy technology that provides temperature controlled energy delivery which should maintain tissue temperature approximately at 100 degree Celsius.
- Advanced RF Energy hand instruments with technology to deliver high compression uniformly across seal area.

Above features are available only in GEN11 and we are the sole manufacturer of this product worldwide and hence it is a proprietary item manufactured by Ethicon Endo-surgery, a Johnson & Johnson company.

Thanking you and assuring you best of our services at all times.

Yours sincerely

jay Bijani Authorised Signatory

Sales Manager

**Ethicon Endo Surgery** 

Johnson & Johnson Medical India



475 CALLE C GUAYNABO, PR 00969 USA

# PROPRIETARY ARTICLE CERTIFICATE

To Whom It May Concern:

This is to certify that Ethicon Endo-Surgery Generator G11, (product code GEN11) is our proprietary item manufactured by Ethicon Endo-Surgery, a Johnson & Johnson Company.

On Behalf of Ethicon Endo-Surgery, LLC For Johnson alchmon

Wendy Turner, RAC Director, Regulatory Affairs

28 June 2011