

All India Institute of Medical Sciences, Jodhpur

No. AIIMSJ-PROCOPROP/24/2023-PROC

Dated: 07th September, 2024

Subject: Proposal for Purchase of Optical Blast Shield and RU 10X Optical Fiber for Holmium Laser 100W, Make Quanta for the Dept. of Urology on Proprietary basis at AlIMS Jodhpur – Inviting Comments/Objection thereon.

The Institute is in the process of purchasing Optical Blast Shield and RU 10X Optical Fiber for Holmium Laser 100W, Make Quanta for the Dept. of Urology on Proprietary basis at AIIMS, Jodhpur from M/s Quanta System S.p.A., Italy though its authorized distributor M/s Unique Medical Devices, Gurgaon. Further, M/s Unique Medical Devices, Gurgaon has authorized M/s Jaidata Enterprises, Jodhpur as authorized dealer. The proprietary certificate submitted are attached & uploaded on website.

The above documents are being uploaded for open information to submit objection, comments, if any, from any manufacturer regarding proprietary nature of the above said Optical Blast Shield and RU 10X Optical Fiber for Holmium Laser 100W, Make Quanta for the Dept. of Urology within 21 days from the date of issue/uploading of the notification. The comments should be submitted only on email address procurement.aiimsjodhpur@gmail.com and hard copy of the same at the office of Admin. Officer, AIIMS Jodhpur on or before 27th September, 2024 up to 03:00 PM, failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Administrative Officer

Enclosure: Related documents enclosed.



June 28th, 2024 Samarate (VA), Italy

To, The Director, All India Institute of Medical Science, Jodhpur

PROPRIETARY TO COMPATIBILITY

Quanta System Optical Blast Shield are compatible with Quanta System Laser systems. Every Laser has different technical parameters and accordingly Optical Blast Shield are designed for the systems. So, other Company's Optical Blast Shield are not compatible to use with Quanta Laser systems. At the same time, we would like to inform that the Optical Blast Shield dedicated to the mentioned lasers are produced exclusively by Quanta System S.p.A.

We hereby also certify that the Optical Blast Shield OAM001523.00 are products and essential standard items manufactured by M/s Quanta System Q1. Italy which are compatible with existing Holmium Laser Model: CYBER HO 100.

Yours Faithfully Dario Bandiera RA Manager Quanta System SpA

QUANTA SYSTEM S.p.A.

SEDE OPERATIVA/OPERATIONAL H.Q.: VIA ACQUEDOTTO, 109
21017 SAMARATE (VA) – ITALY

TEL. +39 0331 376797 – Fex +39 0331 367815

PARTITA IVA/VAT: 10847810188 – C.F.: 01873050122



Oct 10th, 2023 Samarate (VA), Italy

To, The Director, All India Institute of Medical Science, Jodhpur

PROPRIETARY TO COMPATIBILITY

Quanta System Laser Fibres are compatible with Quanta System Laser systems. Every Laser has different technical parameters and accordingly Fibres are designed for the systems. So, other Company's Laser Fibres are not compatible to use with Quanta Laser systems. At the same time, we would like to inform that the fibers dedicated to the mentioned lasers are produced exclusively by Quanta System S.p.A.

We hereby also certify that the Surgical Optical Fibres sterile RU 10x Sterile 272μm surg. Optical Fiber (OAF702313), RU 10x Sterile 365μm surg. Optical Fiber (OAF703613), RU 10x Sterile 550μm surg. Optical Fiber (OAF705513) are products and essential standard items manufactured by M/s Quanta System Q1. Italy which are compatible with existing Holmium Laser Model: CYBER HO 100.

Yours Faithfully **Dario Bandiera** RA Manager Quanta System SpA

QUANTA SYSTEM S.p.A.
SEDE OPERATIVACPERATIONAL H.Q.: VIA ACQUEDOTTO, 109
21017 SAMARATE (VA) - ITALY
TEL. +39 0331 376797 - Fax +39 0331 367815
PARTITA IVAVAT: 10647810158 - C.F.: 01673050122
querta@quartasystem.com - www.quartasystem.com

Newson 30/10/23

Soggetta a direzione e coordinamento di El.En. S.p.A. Sede legale/ Registered office: Via Agnello, 5 – 20121 Milano – Italy Partita IVA/VAT: IT-10647810158 – C.F. 01873050122

SEDE OPERATIVA / OPERATIONAL HEADQUARTER Via Acquedotto, 109 – 21017 Samarate (VA) – Italy Tel. +39.0331.376797 – Fax +39.0331.367815 quanta@quantasystem.com - www.quantasystem.com

Exclusive Distribution Agreement

Urological Products

QUANTA SYSTEM SpA

Via Acquedotto 109 - 21017 Samarate - VA ITALY a company organized and existing under the laws of Italy (hereinafter QS)

and

UNIQUE MEDICAL DEVICES

324, 3rd Floor, Vipul Business Park Central Park Road 2, Sector 48
Gurgaon, Haryana 122004
India

(hereinafter "Distributor")

herein collectively referred to as the "Parties"

WITNESSETH

WHEREAS, QS desires to appoint *Distributor* as its exclusive distributor of the *Products* (see point 1.2) for the *Territory* (see point 1.3) and to sell such Products to *Distributor* for purposes of resale by *Distributor* within the *Territory*;

WHEREAS, *Distributor* desires to act as the *Distributor* of the *Products* in the *Territory* and to purchase such Products for purposes of resale to end-users within such Territory;

NOW THEREFORE, in consideration of the premises and covenants herein included, the *Parties* agree as it follows:

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1. DEFINITIONS

1.1 Marketing Years

This agreement (the "Agreement") shall enter into force upon the date of its signature by both *Parties* and will cease its validity after 05 years unless earlier terminated in accordance with the provisions of this Agreement.

The "First Marketing Period" begins on 1st January 2021 and terminates 12 (twelve) months later unless differently specified.

Subsequent Marketing Periods shall refer to each period of respectively 12 (twelve) months following the preceding Marketing Period.

After the second Marketing Period, which ends on 30th December 2026, the present Agreement will be considered expired and it will not be automatically renewed, but it can be renewed by a letter of renewal undersigned by both Parties.

At no condition, the present Agreement shall be considered automatically renewed. For expiration or early termination, please refer to the terms described at paragraph 7 of the present Agreement.

1.2 Products

"Products" means the QS medical devices and accessories as specified at the following Paragraph 10 of the present Agreement.

QS may, upon 3 (three) months' notice, expunge from the list of *Products* one or more of the *Products*. Exercising such a right shall not involve the resolution of the relationship, which shall continue with regard to the sale of the remaining *Products*. QS is also allowed to apply to the *Products, technical* changes and in that case, QS shall promptly notify such changes to *Distributor*.

The *Distributor* shall not be entitled to raise any objection or claim in said events being understood that the Parties shall take into account the relevant percentage of impact of the elimination of such *Products* and negotiate in good faith a reduction in the *Minimum Purchasing Targets* set forth in Article 10.4 below.

1.3 Territory

"Territory" means the following states:

For LITHO line, Cyber Ho line, Fiber Dust: all states of INDIA excluding the South Indian states: Karnataka, Telangana, Andhra Pradesh, Kerala, Tamil Nadu and Pondicherry.

For Cyber TM line: all Indian states.

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Any deal made by *Distributor* out of the *Territory*, must be previously authorised by QS authorized representatives in written form.

2. MARKETING

2.1 Marketing Rights

- **2.1.1** QS hereby grants to the *Distributor* the right to sell, install, maintain and repair the *Products for the Application* within the *Territory* during the period of validity of this Agreement.
- **2.1.2** Distributor agrees to use its best efforts to promote, sell, install, maintain and repair efficiently the *Products* in the *Territory* and shall not amend or personalize, or procure to amend or personalize, the *Products* (and/or the relevant labels, instructions and documents) without the previous written consent of QS.
- **2.1.3** Distributor shall operate and be liable for the After-Sales Service on the units of *Products* sold in the *Territory*, according to the terms as specified in the section 6.1 of the present Agreement.
- **2.1.4** According to the needs, the *Distributor* is entitled to appoint sub-dealer or sub-distributor or third parties, for the sale of the *Products* in the *Territory*, whereas *QS* will not be responsible of the agreement between main Distributor and sub-dealers.

2.2 Exclusivity Rights

The following terms must be all respected by both Parties in the period of validity of the present Agreement:

- **2.2.1** On the condition that *Distributor* fully respect all of the terms and conditions of the present Agreement, including but not limited to the achievement of the *Minimum Purchasing Targets set forth in section 10.4, QS* shall not appoint any other *Distributor* for the same *Products and Application* in the *Territory* without the written consent of the *Distributor*.
- **2.2.2** Only upon written agreement between the *Parties* which may not unreasonably denied or withheld, *QS* may conclude directly the sales of its *Products* in the *Territory*, whenever this direct action can be considered necessary. In this case the *Distributor* shall be compensated by a provision on the value of the sale finalized by *QS*. The amount of said provision to be previously agreed in written form by the *Parties*, depending on the value of the deal, shall not exceed the standard discount given to the *Distributor*. Said provision shall be paid by *QS* to the *Distributor* upon the deal is positively concluded and *QS* has been paid by the customer, provided that the *Distributor* has not any outstanding payment to be closed in favour of *QS* in which case *QS* shall be entitled to offset any outstanding payment due to the *Distributor* to *QS* against the discount owed to the *Distributor*



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2.2.3 Only upon written authorization by *QS management, Distributor* can appoint subdistributor in other overseas countries outside the *Territory.* Sales in those countries will concur to the achievement of *Minimum Purchasing Targets* defined for the *Distributor* (see paragraph 10.4).

In any case, Distributor remains liable to grant the full traceability of the *Products* purchased, according to paragraph 6.1, including those which are being installed through sub distributors in overseas countries upon the authorization of QS, the Distributor of a medical device shall each maintain an updated record with respect of each device imported and or sold into the country. Importer is a company other than manufacturer who is responsible for the devices being imported into the Territory for the purpose of sale.

- **2.2.4** The *Distributor* **shall not** promote nor sell, either directly or through affiliated third parties, any product manufactured by other companies that are in direct competition with the *Products* as included in *the following Paragraph 10*, unless expressly authorised by *QS*, by mean of written authorisation letter signed by *QS* authorized Executive Manager.
- **2.2.5** Exclusivity rights of the *Distributor* are only referred to the sale of *Products in the Territory* and for the *Application* as specified in the following Paragraph 10. As such *QS* reserves itself the right to appoint other distributors in the *Territory*, for the promotion and the sales of the other products manufactured by *QS*.
- **2.2.6** In case *Distributor* fails to achieve the *Minimum Purchasing Targets* as specified in the following Section 10.4 of the present Agreement, *QS* shall have the right to cancel the "Exclusivity Rights" as hereby described and to pursue the commercial relationship with *Distributor* on non-exclusive basis.

In this case, the notification of the revoke of the exclusivity to the *Distributor*, must be sent by QS in written form not later than 60 days starting the ending date of the marketing period during which the *Minimum Purchasing Targets* was not reached, as specified in point 10.4

3. PURCHASE PROCEDURES

3.1 Purchasing Forecast

Distributor shall provide QS with a rolling 3 (three) months purchasing forecast of the *Products*. The purchasing forecast shall not be binding for QS.

3.2 Purchasing process

The purchasing process is considered finalized only upon full completion of the following steps:

- (i) Distributor shall send its Product(s) purchase order to QS by written form as an official Purchase Order, it being understood that:
 - a) any Purchase Orders shall be considered valid and effective only if accepted in writing by QS; and
 - b) Unless otherwise agreed in writing between the Parties, *Distributor* shall place the Purchase Order on the basis of the purchasing forecast.
- (ii) QS shall send to Distributor the Proforma Invoice with order acceptance and confirmation of delivery date.

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- (iii) Distributor shall transfer on QS bank account the relevant amount as specified in the Proforma Invoice.
- (iv) Upon reception of the money on QS's bank account, QS shall deliver the goods according to the terms specified in the Proforma Invoice.
- (v) If it is unable to guarantee a Purchase Order, QS undertakes to promptly inform Distributor and to take all possible actions to prepare and dispatch any such order in the reasonable timeframe possible. The Parties agree that should any delay by QS trigger the cancellation of one or more orders by customers, QS shall not be held liable in any case for any damage suffered by Distributor.
- (vi) in case of Products distribution in more than one country/area among those provided as "Territory", the Distributor shall inform QS the specific destination country for each Product, in order to determine the proper reference labelling and instructions for use in the official local language(s) before QS order acceptance. QS may decide, at it's sole discretion to proceed with the translation of the labelling and the other documents related to the products, in the local languages of countries of final destination.

For all the other cases, unless differently specified within this contract, English language will be used as reference language for labelling and instruction for use.

3.3 Delivery of Products - Acceptance

3.3.1 Unless differently agreed between the parties in written form, all *Products* and Services and Replacement parts will be delivered by *QS at QS's* warehouse located in Via Acquedotto 109, Samarate, Italy, under the Ex-Works Incoterms (EXW Incoterms 2020) and title and risk of loss, damage or delay shall pass to *Distributor* accordingly. *Distributor* shall be responsible for the payment of all shipping expenses, insurance during the shipment, and all customs duties as so as all import / export fees and tariffs, whereas existing, with respect to all orders of *Products* and Services and Replacement parts.

Delivery times by QS shall not be of essence. Unless agreed otherwise in writing, all Products ordered by Distributor shall be packed for shipment and storage in accordance with QS's current commercial practices.

3.3.2 Distributor will promptly inspect the *Products* on receipt and will notify *QS* of any non-conformity with the relevant Purchase Order within and no later than 15 (fifteen) days of receipt of the *Products*. *Products* shall be deemed accepted unless *QS* receives a written notice of deficiencies within such 15 (fifteen) days period. *Distributor* shall retain any non-conforming *Product* in its original packaging for inspection by *QS* or its insurer and shall make any such non-conforming *Product* available for such inspection. If *QS* agrees with *Distributor* that the shipment is non-conforming, *QS* shall, at its option and at no additional expense to *Distributor*, repair or replace the non-conforming shipment so that it does conform to the applicable Purchase Order.

3.4 Retention of Title

The delivered goods remain the property of QS until all the unsettled claims of QS are paid.

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4. PROMOTION, SALES AND MARKETING MATERIAL

4.1 Copyrights and Ownership of Marketing Material and other documentation

All documents, sensitive information, specifications, prices, drawings and illustrations disclosed by *QS* to *Distributor*, prior to and after the signature of the present Agreement, are property of *QS* and Confidential Information as set forth in section 12 below. As such they must not be disclosed to any third party without the written consent of *QS*.

QS is the exclusive owner of all copyrights and all titles and rights related to all the contents of the website www.quantasystem.com and the other marketing materials such as brands, logos, images, graphics (including those with Quanta watermark), videos, texts, product names either registered or not, web pages with the prefix name of Quanta -xxx, all landing pages with the names of the products manufactured by QS, catalogues and brochures, pricelists, manuals and all other documents either in digital or paper form, created by QS with the purpose to promoting the brands of QS and the Products manufactured by QS on internet, including but not limited to social media channels, such as Instagram, Facebook, Linkedin, YouTube etc... as so as during international or local meetings with distributors and potential customers, in brief "the copyrighted marketing material".

Upon the request of the Distributor, QS authorizes the *Distributor* to the use of "the copyrighted marketing material" belonging to QS, only in order to promote all sales of QS' *Products* as included in the present Agreement.

This authorization is granted to the *Distributor* for the duration of the present Agreement. At the expiration or at the earlier termination of the present Agreement, for whatsoever reason, such authorization will be immediately withdrawn, and all the "copyrighted marketing material" shall be returned to the availability of QS, having the *Distributor* no more right to use it.

During the course of validity of the present Agreement, the *Distributor* may require to QS to make some modifications to the "copyrighted marketing material" in order to make it more suitable to specific needs and the use in the local market, however each modification requested, including but not limited to translations in local languages, shall be submitted to QS' Marketing Department for prior approval.

Therefore, the Distributor is required to provide to QS a preview of any new graphic design, structure and content of the final layout of such modified marketing material, before the final official release by mean of any media.

In any case, the final approval of such modification remains at sole discretion of QS who may deny the same or may require to the *Distributor* to change in part or in total such modified marketing material, before releasing the authorization for publication.

In the event that *Distributor* creates or modifies the "copyrighted marketing material", using *QS* names and brands, whether registered or not, without informing *QS* and without requesting its prior approval and written authorization, the *Distributor* will be held liable for breach of the

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Agreement and the Agreement itself will be immediately terminated for breach. In the latter case QS reserves the right to claim indemnifications and compensations for any material and intangible damage that QS may have suffered as a result of such a violation of the Agreements.

QS takes no responsibility with regard to the accuracy of the information included in the modified marketing material that is being translated in local languages by the *Distributor*, whereas the same were not authorized by QS management in written form, therefore the use of such information and translated content shall be under the sole responsibility of the *Distributor*.

It remains understood that *Distributor* shall be responsible for the compliance of the "copyrighted marketing material" and the modified "copyrighted marketing material" with the applicable national law and regulations in the Territory. QS takes no responsibility with regard to the content and/or the translation of the modified "copyrighted marketing material", either approved and authorized by QS or not; therefore the use of such modified "copyrighted marketing material" and translated content shall be under the sole responsibility of the Distributor. However, any modification and/or translation by *Distributor* of any "copyrighted marketing material" shall be owned by QS.

Distributor agrees to reasonably assist QS in the protection, registration, and defence in the Territory of all "copyrighted marketing material", and to notify QS promptly of any unlawful competition or infringement or potential infringement of the "copyrighted marketing material" of which it becomes aware. Distributor agrees not to contest the validity of any "copyrighted marketing material" now or hereafter used or claimed by QS.

4.2 Distributor's obligations:

- 4.1.1. Distributor hereby represents, warrants and undertakes to:
 - (i) use its best endeavours to develop a market for *Products* in the *Territory*, diligently promote and develop the sales of the *Products* in the *Territory* in compliance with the terms of this Agreement, the merchandising policies of *QS* from time to time and all applicable laws and regulations;
 - (ii) purchase the first package of *Products* units within 90 days from the date of signing the Agreement and be active in communication/purchasing of units (products) /purchasing of spare parts on a quarterly basis.
 - (iii) submit quarterly to QS, in a form satisfactory to QS, an inventory and sales reports listing (a) the quantities of the *Products* sold and (b) the details of all customers (including *Product* codes and number of units) to whom *Distributor* has sold *Products*;
 - (iv) attend and promote the *Products* at its own costs at all significant trade shows in the Territory, also by setting up all the necessary stands to promote the *Products*;
 - in promoting the *Products*, use only the marketing materials provided by or agreed with QS;

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- observe all applicable laws including for the avoidance of doubt, all relevant (vi) nationally recognized industry codes of ethics and guidelines on the promotion of Products:
- observe all reasonable directions and instructions given to it by QS in relation to (vii) promotion and advertisement of the Products, and shall not make any statement, representation or warranty as to the Products, including, without limitation, as to the quality, manufacture, use or application of the Products without the prior written approval of QS;
- maintain in the Territory adequate sales, service, maintenance and office force and (viii) facilities to meet market requirements;
- purchase and maintain a minimum and appropriate stock of Products and spare (ix) parts to ensure supply. Distributor shall ensure a good management of spare parts and regularly order quantities thereof. Without prejudice to the foregoing, Distributor shall maintain storage facilities in accordance with applicable requirements and use all reasonable endeavours to manage an inventory of Products and spare parts to fulfil its obligation towards customers and serve efficiently their needs throughout the Territory;
- frequently train Distributor's employees on anti-bribery and anti-corruption rules and (x) regulations as outlined in this Agreement. QS can request Distributor to provide documentary evidence of conducting such trainings. In the event that Distributor fails to take such mandatory training, then QS may, at its discretion, terminate this Agreement in whole or in part upon 30 (thirty) days' prior written notice.
- 4.1.2 Whenever necessary, the Distributor shall obtain, at its sole cost and expense, all required product registrations, licenses, permits, authorisations, consents, and approvals necessary for Distributor to import and distribute Products in the Territory.
- 4.1.3. Distributor engages himself to promote efficiently the sale of the Products, by means of advertisements, exhibitions, congresses, workshops, presentations and the like, as well as by any other means deemed suitable for this purpose. QS shall supply the Distributor with all advertising material available in English language, such as data sheets, catalogues and so on, in such quantities as may be deemed reasonable by QS and by Distributor.

Upon the request of QS, Distributor engages himself to support QS with the translation into the local language of the QS website content (upon request of QS), documents, such as manuals, catalogues, clinical studies and articles, needed to develop the business in the Territory.

Distributor shall supply QS with full information and all necessary and useful data to establish the basis by mutual consent and in the common interest for developing in the best way the sales. In particular, Distributor shall supply QS every 3 (three) months and/or upon QS simple request with a detailed report on sales forecast, progress made, market situation, competitor's selling prices and, where possible, an evaluation of competitor's sales turnover, contacts taken with customers.

4.2 Sanitary Registration

If necessary, *Distributor* shall support QS with the process of Registration of the *Products* at the local Sanitary Health Authority.

The cost of such registration (if any) shall be paid by *Distributor*, who should report to *QS* about the precise amount of the registration costs for every registered product, immediately after the registration clearance is released.

QS shall provide to *Distributor* with all the documents relevant to the products that need to be registered at the Sanitary Register.

In case of termination of the Agreement, *Distributor* commits to assign to QS or future QS distributors in the Territory, all the rights and titles related to the registration for all registered products and import licenses of the *Products* in the country.

5. SERVICE TRAINING AND QUALIFICATION

It is mandatory for the *Distributor* to have technical personnel duly trained with specific reference to first product start-up, use, maintenance and repair of the *Products*.

QS shall provide adequate training for *Distributor*'s designated specialists, with specific reference to first product start-up, use, maintenance and repair of the *Products*.

Said training courses to be set up and take place at QS's facilities in Samarate (VA), Italy, will be provided by QS at no charge for the Distributor, whereas all travel and accommodation costs of Technical Personnel attending the courses shall remain at Distributor charge.

Distributor shall send qualified technicians to QS premises to attend the Service Training before or within 1 (one) month from the first product start-up of the first unit.

Depending on the specific platform, upon QS agreement, the combination of User/Service manual and the technician's expertise could be suitable to perform installation or routine service activities.

Since Service trainings will be performed in English language, it is mandatory that the attendees should be qualified technicians/engineers with excellent knowledge of English language, to allow appropriate understanding.

At the end of above-mentioned Service Training, the contributors will take a Verification Test. A positive result/feedback is necessary to allow QS to issue a Qualification Certificate.

Training may be performed by Quanta System or internally. At least one of the Distributor technicians shall be trained by Quanta System.



The qualified technical personnel of Distributor, can, under their responsibility, qualify other technical personnel of Distributor.

Note that internal training registrations may be requested by Quanta System.

Only qualified technical personnel of Distributor will be authorized to make technical service interventions on Products.

QS reserves itself the right to request to the *Distributor* to send again the same or other technician(s) in case the technicians who attended the service training do not fulfil all the requirements.

All Service Trainings should be scheduled and attended by the technical personnel of the *Distributor* upon the need, according to *QS* Training schedule.

For all the operations related to the Service of *QS* equipment, the *Distributor* must strictly observe all the instructions and the indications provided by *QS* Technical and Service staff and included in the official documentations such as Service and User manuals, supplied with the *Products*.

QS shall not be responsible for any damage resulting from operations which should be conducted on the *Products* by NON authorized personnel and /or NON in compliance with the technical instructions provided by *QS*.

If the qualified technical personnel of Distributor is unable to perform a specific repair activity, the Distributor may require, as an exception, the direct support from QS.

In this case QS may dispatch a service technician according to QS timetable and availability and upon agreement of the intervention costs with the Distributor

The present Agreement can be considered void if the *Distributor* would not be able to assist its customers in the *Territory*, which may damage the image of *QS* brand name and the reputation of the *Products*.

6. AFTER-SALES SERVICE

6.1 After-Sales Service

Distributor shall perform the first product start up and after-sales service for all end-users in the Territory. QS may ask Distributor to perform After-Sales Service for the end-users who have bought the Products prior to or during the validity of this Agreement.

Such operation must be performed exclusively by technical personnel who has been qualified by QS (see Paragraph 5) or has been recognized by QS as qualified personnel.

To this purpose, Distributor shall notify to QS the list of qualified personnel who is authorized by Distributor to perform the Technical Service on the Products.



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Within 15 days from the First Start-up of the Products, the Distributor must send to QS's Service Dept. a complete Report related to the Products, signed by Technical Personnel in charge. A missing report from the Distributor, within terms above mentioned, may cause annulment of the manufacturer's Warranty with QS reserving the right to charge the Distributor for all the relative costs.

In addition to the First Product Start Up Report, Distributor must send to QS's Service Dept. a quarterly summarized Report which include a list of all technical interventions made on the Products.

In order to grant full traceability of the Products, the Distributor of a medical device shall each maintain an updated record with respect of each device imported and or sold into the country. Importer is a company other than manufacturer who is responsible for the devices being imported into the Territory for the purpose of sale.

Distributor is a company, other than a manufacturer or a retailer, who sell or rent the device in the Territory for the purposes other than for its own use.

Importer could also act as a distributor.

Distributor must handle and update the list of all the installed devices with the location addresses of the end users.

Such record shall contain sufficient information to permit complete and rapid withdrawal of the medical device from the market in case of need.

The importer/distributor shall retain the distribution record maintained in respect of a medical device for minimum 10 (ten) years after the date the device is shipped, regardless of the Contract validity.

Moreover, Distributor agrees and accepts without conditions to follow all the instructions communicated by QS concerning safety items.

Every 3 (three) months the Distributor must send to QS a report which includes a list of the customers, the location address and eventually the services made with a detailed list of the replaced components.

The First Start-Up of the device must be considered as the first service with its own report.

6.2 Warranty

QS warrants that the Products, at the time of the delivery to the Distributor's shipping agent at Samarate, Italy, shall be free from defects in materials and workmanship.

The Standard Warranty Period for brand new spare parts and/or finished goods is 12 (twelve) months upon the first start-up of the devices as stated in the service report that must be sent to QS Service Department (see paragraph 6.1).

Unless differently specified by QS, Standard Warranty period expires automatically after 13 months upon the delivery date as reported in the shipping documents. Refurbished parts are covered by 6 months warranty period upon the first start-up date and no

more than 7 months upon the delivery date.

Warranty extensions can be requested and are subject to be agreed by the Parties in written form.

QS's obligation and liability under this warranty is limited only to repair or replacement of defective parts, which shall be removed from the Products by Distributor and returned to QS, at Distributor expense, with all shipping and insurance charges prepaid.

In case of need, upon availability of goods and at the sole discretion of Quanta Service Manager, Quanta may ship in advance the spare parts and other material requested for replacements under warranty. In such case the goods will be shipped on loan basis, based on the condition that the Distributor will return to Quanta the faulty items within 30 days upon the receipt of the goods to be replaced under warranty. In case Quanta will not receive the prove that the goods to be returned has been shipped back after 30 days, Quanta will issue a sales invoice to the Distirbutor and will not accept anymore the shipment of the faulty items in return.

Freight charges, custom duties and all expenses related to the shipment of warranty replacements, remain at Distributor charge.

The faulty items must be sent back to QS within 30 days from the receipt's date of replaced parts, at Distributor expense, with all shipping and insurance charges prepaid. Custom duties in Italy remain at QS charge.

In the case of incomplete or wrong supplying, defective products or faulty items, which are found and notified to QS within 15 days upon the reception of the goods at destination, QS will pay all the shipping costs related to the delivery of the replacement parts and the return of the faulty or wrong items back to Italy.

All other guarantees, warranties, conditions and representations, either expressed or implied, whether arising under any statute, common law, commercial usage or otherwise, including implied warranties of merchantability and fitness for particular purpose, are hereby excluded.

6.3 Exclusions

Accessories and consumable parts, such as flash lamps, water filters, deionizing cartridges, all surgical fibers and all parts subject to mechanical deterioration not included in the standard warranty and they are subject to be replaced under warranty only in case of malfunctioning or defect of manufacturing that should show up immediately after the reception of the goods.

Standard warranty does not cover the following cases:

- Damages due to misuse and /or abnormal use
- Damages due to tampering caused from personnel who is not qualified and/or not authorized by QS
- Damages due to accident occurred after the goods left QS warehouse
- Damages due to wrong or incomplete maintenance, either standard or extraordinary
- Damages due to wrong Start-Up procedures
- Damages due to wrong or missing observance of all User, Service and Application procedures described in the manuals provided by QS.

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6.4 Tools Kit

In order to provide a correct and effective after-sales service, the Distributor's technical personnel shall use priority Tools, indicated by QS during the Service Training.

These tools are the same used by QS's Technical Personnel.

Distributor, if not already in possession of such tools, shall buy the same from QS prior to or latest at the moment of placing the first purchasing order of devices, to make sure to have the right tools to install such devices once delivered.

Distributor is responsible to use calibrated instruments. Monitoring and measuring equipment used for service activities must be calibrated or verified, as appropriate, at specified intervals. Upon request of QS, Distributor shall provide to Quanta prove of the calibration test performed

6.5 Service Parts

Distributor engages himself to keep in his inventory, Spare Parts of QS Products in reasonable quantity to carry out efficiently the After-Sales Service.

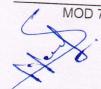
QS will use its best efforts to ship Service and Replacement Parts at the earliest possible date. QS shall be entitled to terminate this Agreement with immediate effect, and the distributor will lose the distributorship, under the discretion of QS only, if it is demonstrated that Distributor uses for service purposes spare parts and consumables not supplied by QS. In addition, the systems still under warranty, with spare parts, consumables and/or accessories that are not those supplied by Quanta System, will automatically lose the warranty itself.

6.6 Formal notifications and regulatory compliance

Both Parties oblige themselves to proactively become market vigilant, as foreseen by the applicable laws and regulation in force in the Territory where the Products are distributed, along with the after-sales surveillance of medical products, as part of this Agreement, to mutually

- a) Problems related to safety and performance of medical devices and any consideration related to the clinical use of the same devices, along with any updating of the clinical state-of-the-art of any application (including new ones) made in conjunction with the medical devices themselves.
- b) Customer complaints coming from the market.
- c) Incidents or any potential situation which could have led to an incident, that could have caused or could cause the serious injury or the death of patients, users or any third parties who for whatsoever reason may be involved with the use of our devices.
- d) Lack of instructions related to the use of the device, which could lead to an incorrect use of the device itself with potential risks for patients and operators.
- e) The necessity of recalling devices from the field of use.

All the above information shall be gathered with the aim to put both Parties, QS and the Distributor, in condition to make interventions and to pose remedy, including if necessary, the potential complete and final recall of the devices from the market.



The Parties commit to reciprocally keep themselves updated regarding any potential communication with Health or other Competent Authorities, including the reporting of incidents and situations which could have led to an incident, or any recall from the field of use.

Additional requirements for specific countries/areas may be included in separate annex, as appropriate.

Unless differently agreed, complaints shall be submitted to QS using the official form provided by QS.

The distributor commits to support QS in Post Market Surveillance processes in order to get useful information from the field that are needed for the life-cycle product management and regulatory obligations.

6.7 Recalls

The Distributor hereby undertakes to collaborate fully with QS in relation to the collection and recall of Products on the market further to any Authority request or if requested by QS, it being understood that any and all costs, charges and expenses incurred in relation thereto shall be borne exclusively by QS.

7. TERM AND TERMINATION

7.1 Term

This Agreement shall commence and end according to what is stated in the Section 1.1 and shall continue, unless earlier terminated, as hereby described, until 2 (two) years from the date of signing the Agreement.

7.2 Withdrawal -Termination

7.2.1 Without prejudice to other remedies under law and the Agreement, QS shall have the right to terminate the Agreement pursuant to Article 1456 of the Italian Civil Code, by providing to Distributor a simple written notice thereof, should the Distributor breach any one of its undertakings and/or the representations and warranties made pursuant to clauses 1.3. (sales outside Territory), 2.2.4 (exclusivity- non competition), 4. (Distributor's obligations), 6.1 (After Sale Service), 6.5 (Service Parts), 10.4 (Minimum Purchasing Targets), 11 (Compliance with law), of the present Agreement.

7.2.2 QS shall also have the right to terminate the Agreement by giving written notice to the *Distributor* with effect from the date specified in such termination notice, if:

a) Distributor alternatively:

(i) is subject to any forced execution procedure;

(ii) suspends the payments due to its suppliers and/or employees or admits in writing its temporary inability to pay its debts as they become due;

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- (iii) does not approve and file financial statements and/or fulfil any and all related requirements within the term provided for by Applicable Law;
- (iv) is in the situation provided for by article 2446 and 2447 of the Italian Civil Code;
- (v) resolves its winding up or its capital increase or decrease;
- (vi) announces and/or starts collective redundancy procedures.

In case that the Agreement was terminated for the aforementioned reasons, the import rights for products manufactured or sold by QS, will have to be assigned, unconditionally and free, to QS or to a third party company indicated by QS. This shall occur immediately upon cessation of the rights for distribution. It remains explicitly confirmed that all certifications and registrations of QS products shall bear the name of QS, which will exclusively keep all the rights in terms of property/product registration / filing and clearance.

- **7.2.3** Without prejudice to clause 7.2.1 and 7.2.2, should any Party breach any of its obligations under the Agreement, the other Party shall be entitled to terminate the Agreement pursuant to and in accordance with article 1454 of the Italian Civil Code, by sending the breaching Party written notice of the breach, expressly inviting said Party to remedy the breach within 30 (thirty) days of its receipt of the notice. If the breach is not remedied within such term, the Agreement shall be terminated.
- **7.2.4** Upon the expiry or termination of the Agreement for any reason whatsoever, the *Distributor* shall not be entitled to receive indemnity or any form of compensation, including in relation to any investments made, loss of profits or any increases in customer numbers obtained. The *Distributor* hereby expressly waives any claim or objection in that respect.

7.3 Effect of termination

The following shall apply in the event of expiration or early termination of this Agreement for any reason whatsoever:

- a) Payment obligations of each of the Parties to the other shall survive until fully honoured.
- b) Distributor shall continue marketing of the Products in its inventory unless differently agreed in written with QS.
- c) Distributor shall immediately cease using any trademark, logo, trade name or marketing, promotional or advertising material, whether in connection with any business conducted by Distributor or in which it may be interested or otherwise, provided that Distributor may continue to use any such trade names, trademarks or material after the termination of this Agreement for the sole purpose of selling the Products in its inventory.
- d) Distributor shall immediately cease to carry out the distribution activities other than for the purpose of completing sales pursuant to orders accepted prior to the termination or expiry of this Agreement and will immediately cease to represent itself as QS's Distributor or as having any right to carry out the distribution activities in relation to the Products on an on-going basis and all rights and licenses granted to Distributor under this Agreement shall terminate.

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- e) Distributor agrees to do the following, without compensation, and to the extent not expressly prohibited by law of the Territory: (a) immediately cease using all import licenses related to the Products; (b) transfer without delay to QS's nominee or nominees, upon receipt of QS's written request, all valid import licenses related to the Products; and (c) not seek the granting or extension of such import licenses. Generally, Distributor will assist QS with an orderly transition of any necessary import licenses to QS's nominee or nominees as so as to allow business transactions to continue without interruption.
- f) A final report about all the installed Products as described in the Section 6.1 will be supplied by *Distributor* to *QS*.

8. TRADEMARKS AND OTHER INTELLECTUAL PROPERTY

The Distributor acknowledges that all the industrial and intellectual property rights connected in any way to the Products, including therein relating to the trademarks, patents, copyright, technical data and know-how and their use, including economically are owned and shall be owned, exclusively by QS. Entering into this Agreement shall not provide the *Distributor* with any QS intellectual property right other than the right to use them for the term and on the conditions strictly required for carrying out the activities provided for in this Agreement.

With effect from the expiry, termination or early termination of this Agreement for any reason whatsoever, the Distributor shall not longer have the right to use any QS intellectual property rights in any way whatsoever, except for the sale of the existing stocks of *Products*.

QS represents that it is not aware of any circumstance on the basis of which a third party could make any form of claim against the QS intellectual property rights and that, on the basis of the information in its possession, QS intellectual property rights do not in any way breach third party industrial rights.

The Distributor undertakes to promptly inform QS of any breach of the Qs intellectual property rights by third party or any claim by a third party alleging that the Products or the QS intellectual property rights breach their own rights.

9. GENERAL

9.1 Status of Parties

The Parties are independent contractors, and nothing in this Agreement shall be construed to make the employees of one party, as servants or agents of the other party.

9.2 Successors and Assigns – Change of Control

This Agreement may not be assigned by either Party without the prior written consent of the other Party. It shall be binding upon the successors and assigns of the Parties and shall inure to the benefit of the successors and permitted assigns of the Parties.

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In case the *Distributor* was to be sold in full or in part, or in case the ownership of the Distributor was to be changed under any form, or the Distributor was to take any part to an M&A process, the *Distributor* must immediately inform in written QS.

In such case, QS shall have the right to terminate this Agreement by giving 3 months' written notice to the *Distributor*.

9.3 Notices

All notices and other communications required or permitted hereunder shall be in writing and shall be mailed by registered or certified mail or delivered either by hand or by messenger or sent via telex, telecopy, computer mail or other electronic means, addressed to the address set forth below or to such other address as specified in writing to the Party initiating the notice or communication.

Any notice or other communication so addressed and mailed by registered or certified mail (in each case, with return receipt request) shall be deemed to be delivered and given when so mailed. Any notice so addressed when otherwise delivered shall be deemed to be given when actually received by the addresses:

QUANTA SYSTEM SpA

Via Acquedotto, 109	
21017 Samarate - VA - ITALY	
Tel.: +39 0331 376797	
Fax: +39 0331 367815	
quanta@quantasystem.com	

UNIQUE MEDICAL DEVICES

324, 3rd Floor, Vipul Business Park Central Park Road 2, Sector 48, Gurgaon, Haryana 122004. India

Email - <u>director@uniquemedicaldevices.org</u> Phone - 0124-4080411/8860086235

Mobile: +91-8860086233

9.4 Survival. Termination or expiration of this Agreement will not affect any rights and obligation of the Parties that arose prior to such termination or expiration. In addition, Article 6.7 (Recalls), 7.3 (Effect of Termination), 8 (Trademarks and Intellectual Property), 9.3 (Notices), 12 (Confidentiality),13.1 and 13.2 (Governing Law and Dispute Resolution) survive expiration or termination of this Agreement, provided that the obligations under Article 12 shall survive for the period stated therein

10. PRODUCTS, PRICES AND OTHER COMMERCIAL TERMS

10.1 Products and Prices

Unless differently specified, Distributor shall purchase the Products as specified below:

The

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11. COMPLIANCE WITH LAW

- 11.1 Distributor hereby represents, warrants and undertakes to act at all times in good faith in the performance of this Agreement and specifically to
 - comply at all times with the laws of the Territory;
 - comply in all its business dealings with any applicable code of conducts and code of ethics, including the El.En. code of ethics (which can be found on www.elenlaser.com);
 - maintain accurate books and records and permit QS, on reasonable notice and at QS's expense, to audit Distributor's books and records to verify compliance with the duties set forth in this clause;
 - · immediately inform QS, in writing, prior to any change in ownership or control of Distributor or any controlling person of Distributor;
 - comply with all relevant domestic and international laws, regulations and administrative requirements including anti-corruption provisions (such as Italian Legislative Decree 231/2001, US Foreign Corrupt Practices and the UK Anti Bribery Act), the Legislative Decree 165/2001, those governing trans-border sales, resales, shipments, and transfers of products, including, but not limited, to the export control and anti-boycott laws of the United States and of any other country, to the extent that such laws are applicable, and will take no action which would subject QS to penalties under the laws, regulations, or administrative requirements of the United States or any other country.
- 11.2 Distributor understands that QS places great value on its reputation as an ethical company and its commitment to compliance with applicable laws and by execution of this Agreement, Distributor warrants and certifies that it fully understands QS's conduct with respect to international sales transactions and relations with customers and suppliers.
- 11.3 Distributor warrants that none of the principals, officers or employees of Distributor is a government employee or official, an official or employee of a state-owned business or of any public international organization, a political party official, or a candidate for political office.
- 11.4 Distributor warrants that in connection with the transactions contemplated under this Agreement, Distributor shall neither (i) give, offer or promise to give, or authorize the giving of, either directly or indirectly through any other person or firm, any money or thing of value to any government official such as any employee or official of any government or of any state-owned business, or any employee or official of any public international organization, any political party or official or employee of such party, or any candidate for political office nor (ii) offer or pay or request or accept, in connection with its sales and marketing activities with private as well as public parties, bribes, kickbacks, under-the-table payments or other similar improper payments, or obtain or attempt to obtain business through improper use of business courtesies such as gifts or entertainment of more than token value, or accept such gifts or entertainment.

12. CONFIDENTIALITY

12.1 Each of the Parties undertakes to maintain and procure the maintenance of the confidentiality of Confidential Information of the other Party at all times and to keep and

procure the keeping of all Confidential Information of the other Party secure and protected against theft, damage, loss or unauthorised access, and not at any time, whether during the term of this Agreement or at any time thereafter, without the prior written consent of the other Party, directly or indirectly, to use or authorise or permit the use of or disclose, exploit, copy or modify any Confidential Information of the other Party, or authorise or permit any third party to do the same, other than for the sole purpose of the performance of its rights and obligations hereunder.

12.2 The Parties may have exchanged Confidential Information during pre-contractual negotiations and/or may exchange Confidential Information during the Initial Term and any subsequent term. Each Party shall use Confidential Information of the disclosing Party only as necessary to perform its obligations under this Agreement and shall not disclose Confidential Information of the disclosing Party to any third parties except its employees or agents who need to know such information and who are aware of and agree to comply with the receiving Party's confidentiality obligations under this Agreement, or as reasonably required by any governmental authority, court, or regulatory body.

12.3 The receiving Party shall take all reasonable measures necessary to maintain the confidentiality of Confidential Information of the disclosing Party and to keep such Confidential Information secure and protected against theft, damage, loss or unauthorised access, including using the highest degree of care with which the receiving Party protects its own Confidential Information. The receiving Party shall notify the disclosing Party in writing of any disclosure, misuse or misappropriation of the disclosing Party's Confidential Information which may come to the receiving Party's attention.

12.4 The obligations of confidentiality in this Agreement shall not apply to any Confidential Information which the receiving Party can demonstrate (i) has entered the public domain, except where such entry is the result of the receiving Party's breach of this Agreement, (ii) has been lawfully received by the receiving Party from a third Party on an unrestricted basis, (iii) is known to the receiving Party prior to disclosure (other than through a disclosure to the receiving Party by the disclosing Party prior to the Agreement signing date, or (iv) has been independently developed by the receiving Party.

12.5 The terms and conditions of this Agreement shall be treated as Confidential Information of each Party. Prior written approval by both Parties must be obtained prior to any public announcement or press release regarding this Agreement.

12.6 Upon termination or expiry of this Agreement, or upon written request, the Parties shall promptly return (or destroy upon request) any and all materials and property belonging or relating to the other Party including without limitation all Confidential Information of the other Party (and, in the case of Distributor, marketing and promotional materials provided by QS), and all copies of the same then in its possession, custody or control provided that the receiving Party shall not be required to delete (but shall not be able to use) electronic copies made as part of the receiving Party's routine back-up or archive process.

The

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13. GOVERNING LAW AND JURISDICTION

13.1 This Agreement shall be governed and construed in accordance with the laws of Italy.
13.2 Any dispute that may arise regarding its interpretation, execution and resolution shall be submitted to the exclusive jurisdiction of the Court of Milan (MI), Italy.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

QUANTA SYSTEM S,p.A.

Via Acquedotto, 1 21017 Samarate - VA – ITALY Tel +39 0331 376797 Fax +39 0331 367815 quanta@quantasystem.com

Title: VP Global Sales Name: Mario Annesi

Date:

Signature

QUANTA SYSTEM S.P.A.

Mario Arresi

VP)Salos?

UNIQUE MEDICAL DEVICES

324, 3rd Floor, Vipul Business Park Central Park Road 2, Sector 48,

Gurgaon, Haryana 122004, India

Email - <u>director@uniquemedicaldevices.org</u> Phone - 0124-4080411/8860086235

Mobile: +91-8860086233

Title: Managing Director Name: Prakash Singh

Date:

Signature

Pursuant to and for the purposes of Articles 1341 and 1342 of the Italian civil code, the Distributor declares to have carefully read, understood and to specifically approve the following provisions of the Agreement: 2.2.2 (payments offset), 3.2.5. (Delivery), 9.2. (Successors and Assigns – Change of Control), 10.1 (Price changes), 10.2 (Payment), 13.1 (Governing Law) and 13.2. (Jurisdiction)]

Date

signature



Ref: UMD/2023-24/AIIMS-JODHPUR/PC-07

Date: 01/04/2024

To,
The Director,
All India Institute of Medical Science,
Jodhpur

Subject: Manufacturer's Authorization Letter

Dear Sir,

We, M/S Unique Medical Devices, having registered office at 323/324 3rd floor Vipul Business Park, Sector-48, Sohna Road, Haryana-122004 hereby authorized JAI DATA ENTERPRISES, Shop No. 11 Gandhi Tower, Jalori Bari Jodhpur 08-Rajasthan Phone 9929726851/8058001233 to quote, supply reagents, consumables & controls & to raise bills and collect payments for entire AIIMS JODHPUR.

We further confirm that no supplier or firm or individual other than M/S JAI DATA ENTERPRISES is authorized to supply, raise bills & collect payment, for entire AIIMS JODHPUR

This Authorization is valid till 31.12.2024

Thanking You

For Unique Medical Devices

Authorized Signatory