Role and Responsibility Agreement for Devices

This Role and Responsibility Agreement for Devices (the "Agreement") is made and entered into as of December17,2024 (the "Effective Date") by and between Qisda Corporation, having its principal place of business at157 Shan-Ying Road, Gueishan, Taoyuan 333 ("QTY"), Qisda Electronics (Suzhou) Co., Ltd.., having its principal place of business at [169 Zhujiang Road, New District, Suzhou, JiangSu, China] ("QCES") (QTY and QCES shall collectively be referred to as "Qisda") and DIVA Laboratories, Ltd, Diva having its principal place of business at 9F. No.351, Sec. 2, Zhongshan Rd, Zhonghe Dist., New Taipei City 235 (" Diva"). Qisda, QCES and Diva are hereinafter referred to jointly as the "Parties" and each as a "Party.

WHEREAS,

This Agreement defines roles, responsibilities and the quality system requirements ("Product") provided in support of the manufacture and distribution of finished devices or accessories to finished devices, as defined by ISO 13485 .

This Agreement and the information contained in it is proprietary and confidential information of both Parties. Any unauthorized use, duplication, modification, and disclosure of it is strictly prohibited and subject to the restrictions of the confidentiality agreement between the Parties.

This Agreement is intended to serve as a guide for use in the development of the Products to address the manufacture and supply of components, products and services.

[Note] For any section(s) deemed not applicable, state N/A and provide an explanation in the comments column of why this activity is not within scope of this Agreement.

1. Parties Involved

- DIVA Laboratories, Ltd. (Diva)
- Qisda Corporation (QTY)
- Qisda Electronics (Suzhou) Co., Ltd.

2. Policies, Standards, Regulations

This Agreement shall apply only if all qualifications and authorizations required for each party to perform and carry out the activities hereunder have been received.

Parties shall establish and maintain procedures in compliance with their respective Quality Systems and with Quality System Regulations applicable to the countries where the product is distributed. At minimum, the following Regulatory requirements shall be met: (Latest as applicable)

- ISO13485, Medical devices - Quality management systems - Requirements for regulatory purposes

3. Scope

This Agreement applies specifically to activities performed in support of Products manufactured for - DIVA Laboratories, Ltd by Qisda.

The activities covered by this Agreement are detailed in the tables below. Collectively, these activities will be referred to as "Service" or "Services" in this Agreement. This Agreement will be maintained by both Parties.

The Products covered by this Agreement are as follows:

1)
Product name: RGD2461AMI
Brand name: Philips
Model name: RGD2461AMI
Model number/ Regulatory name: RGD2461AMI

2)
Product name: RUG6513AMI
Brand name: Philips
Model name: RUG6513AMI
Model number/ Regulatory name: RUG6513AMI

3)
Product name: RUG5513AMI
Brand name: Philips
Model name: RUG5513AMI
Model number/ Regulatory name: RUG5513AMI

4)
Product name: Shelby
Brand name: Philips
Model name: Shelby

Model number/ Regulatory name: Shelby

5)
Product name: RGT2422AMII
Brand name: Philips
Model name: RGT2422AMII
Model number/ Regulatory name: RGT2422AMII

6)
Product name: VM18
Brand name: Philips
Model name: VM18
Model number/ Regulatory name: VM18

7)
Product name: VM19
Brand name: Philips
Model name: VM19
Model number/ Regulatory name: VM198)
Any other device or display products agreed among the Parties and specified in an appendix, which shall, upon full execution thereof, be deemed to be a part of this Agreement and governed by the provisions hereof and the additional provisions set forth in such appendix.

4. Roles & Responsibilities

Diva: DIVA Laboratories, Ltd
Qisda: Qisda Corporation, Qisda Electronics (Suzhou) Co., Ltd.

4.1 Monitor High level Responsibilities

4.1.2 Monitor High level Responsibilities for ISO13485	Diva	Qisda
Manufacturer *A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.*	V	
Importer *Natural or legal person in the supply chain who, is the first in a supply chain to make a device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.*	V	
Distributor *Natural or legal person in the supply chain who, on this own behalf, furthers the availability of a device to the end user.*	V	
Authorized Representative *Natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's Obligations under that country or jurisdiction's legislation.*	V	

5. **Management Plan**

Table below defines the requirements and frequency for key elements of the Diva and Qisda relationship.

Note: For any Quality System Activity described below as "Not Applicable" to the scope of the agreement, or not specifically called out in this agreement, Diva and Qisda are each responsible to ensure activities related to these activities are carried out in accordance with their own established quality system.

Quality System Activity	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Quality Agreement Maintenance	Review, approve, and maintain this document.	Review, approve, and maintain this document.
Quality Management Review	Management Review per Diva established process.	Management Review per Qisda established process.
▪ **major business change** ▪ **facility change** ▪ **management personnel changes** ▪ **changes of operations/ relocation/ functional outsourcing**	Proactively notify Qisda of the changes listed in the front column that may impact the relationship and/or this Agreement.	Proactively notify Diva of the changes listed in the front column that may impact the relationship and/or this Agreement.
complaint handling & adverse event reporting	When aware of any potential reportable event, responsible to notify Qisda within 2 Business days. Also as distributor reporting responsibilities when appropriate.	Responsible for complaint handling, adverse event determination and reporting in accordance with established procedures. While reporting, Qisda has to make sure a communication has been made to Diva.

Quality System Activity	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Reporting of Corrections and Removals(C&R)	Responsible for execution C&R in accordance with established procedures. Responsible for maintaining customer data and providing the user affected list.	Responsible for reporting of C&R in accordance with established procedures. Responsible to provide information related to affected serial numbers to execute C&R.

6. **Quality System Requirements**

6.1 Design Controls	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Design Approval	Diva is responsible for and shall obtain the client's written approval for all designs and specifications.	Qisda shall receive the specifications for design, manufacturing, parts, and inspection only from Diva.
Design Change	Diva will request some changes related to Diva branding and specific user preferences. All changes shall be approved in writing.	Shall obtain Diva's written approval for agreed parts or any modification to Product specifications.

6.2 Document Controls	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Document Change Control	Documentation related to Product changes/ approvals will be stored within Diva documentation system and Diva shall deliver such documents to Qisda.	Qisda shall not, without Diva written approval, modify product or process specifications in a manner that affects final product performance and/or regulatory approval status. Qisda shall maintain records of changes to documents.

6.2 Document Controls	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Record Retention	Per Diva existing Quality Management System. Diva shall provide the information of expected life of device to Qisda. Product expected life: 10 years.	Per Qisda Quality Management System, all product records must be maintained for a minimum of 10 years beyond end of life of the product or as governed by regulatory agencies for different markets whichever is higher.

6.3 Purchasing Controls	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Supplier Controls	Review, evaluate, and accept or reject proposed changes to component sources by Diva. For any components sourced by and/or operations performed by Diva, purchasing controls shall be handled per established purchasing control procedures. Changes to component sources shall be handled per the applicable purchasing controls and change control requirements.	For any components sourced by and/or operations performed by Qisda, purchasing controls shall be handled per established purchasing control procedures. Changes to component sources shall be handled per the applicable purchasing controls and change control requirements.
Management of Qualified Vendor List (QVL)	Responsible to maintain the QVL at Diva. Diva shall decide and obtain the client's written approval for any specification change, and notify Qisda by formal email notice. Material No. "EM.xxxxx.xxx": Diva inspects and manages component incoming quality.	Responsible to maintain the QVL at Qisda. Material No. TY.xxxxx.xxx, Qisda inspects and manages component incoming quality in accordance with Diva's specifications.

6.4 Identification and Traceability	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Product Traceability	Responsible to ensure product traceability is maintained throughout their processes.	Responsible to ensure product traceability is maintained throughout their processes.
Product Identification during Operations and Service Supply	Responsible to ensure product traceability is maintained throughout their processes.	Any non-conforming material shall be clearly identified and segregated as required by existing quality management system processes.
Recording of Unique Device Identification (UDI)(if applicable)	Product UDI will be captured in install base records.	Product UDI will be captured in DHR.

6.5 Production and Process Control	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Initial Release of Product Related Quality Documents (work instructions, test instructions)	Not applicable	Responsible for defining and maintaining the manufacturing process and associated controls for those processes performed. Should maintain same per their Quality Management System process.
Environmental Control Conditions (manufacturing)	Not applicable	The work environment will be determined and managed by established Qisda environmental control procedures as applicable.
Control of Production, Monitoring, and Measurement Equipment	Not applicable	Responsible for control of any measurement equipment used in its own processes.
Process Validation	Responsible for process designed or specified by Diva	Responsible for validation of any processes it performs.

6.6 Acceptance Activities	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Receiving / Incoming Acceptance	Not applicable	Responsible to ensure that purchased product meets specified requirements in accordance with documented and established QMS processes and procedures. (Follow Note 6.3)
In-process Control	Not applicable	Responsible to ensure Product meets specified requirements in accordance with documented and established QMS processes and procedures.
Final Acceptance & Release for Shipment Distribution	Not applicable	Responsible to ensure that Product meets specified requirements in accordance with site documented and established QMS processes and procedures for final inspection and test. Identification and control of nonconforming product will be conducted in accordance with nonconforming product control procedure of Qisda.

6.7 Nonconforming Product	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Product Disposition	Not applicable	Non-conforming material at receiving inspection, in-process or final inspection will be processed and dispositioned using established procedures.

6.8 Corrective and Preventive Action	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Corrective & Preventive Actions	When made aware of a potential reportable event, responsible to notify Qisda. Distributor is responsible for reporting where appropriate.	Responsible for complaint handling, Adverse Event determination and reporting in accordance with established procedures. While reporting, Qisda has to make sure a communication has been made to Diva.
Corrective & Preventive Actions	Responsible for following Diva quality system CAPA procedures.	Responsible for following Qisda quality system and CAPA procedures.

6.9 Labelling and Package Control	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Product Labels and Packaging	Responsible for providing any requirements for Product packaging and labelling.	N/A
User Manual	Responsible for user manual content.	N/A

6.10 Handling, Storage, and Distribution	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Handling	Diva shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to Product do not occur during handling.	Qisda shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to Product do not occur during handling.

6.10 Handling, Storage, and Distribution	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Storage	Diva shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate. b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.	Qisda shall establish and maintain procedures for the control of storage areas and stock rooms for Product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of Product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate. b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.
Distribution	Diva shall maintain distribution records which include or refer to the location of: 1) The name and address of the initial consignee or end customer ; 2) The identification and quantity of devices shipped; 3) The date shipped; and 4) Any control number(s) used.	Qisda shall maintain shipping records which include or refer to the location of: 1) The name and address of the initial consignee; 2) The identification and quantity of devices shipped; 3) The date shipped; and 4) Any control number(s) used.

6.11 Post-Market / Complaints	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Complaint / Incident Handling	Responsible for product complaint communication to Qisda and track closure, including: 1. Device identification(product name, model and serial number) 2. Customer information (name, address and phone number). 3. The nature and details of the complaint. Responsible for product complaint handling and incident reporting in accordance with established procedures. Responsible for the maintenance and storage of complaint files and other applicable documentation associated with a complaint investigation. Responsible to document the investigation, including root cause analysis, when complaint is related to products or services covered under this Agreement.	Responsible for product complaint handling and incident reporting from Diva in accordance with established procedures. Responsible for the maintenance and storage of complaint files and other applicable documentation associated with a complaint investigation. Responsible to document the investigation, including root cause analysis, when complaint is related to products or services covered under this agreement.

6.11 Post-Market / Complaints	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Returned Product Analysis	Responsible for returned product preliminary analysis and provide adequate information.	Responsible to analyse returned material upon request. Responsible for coordinating product analysis for complaint investigations and forwarding of the appropriate information to Diva.

6.12 Servicing	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Product Servicing	Responsible for final product service support and documentation.	Responsible for support for spare part availability.

6.13 Statistical Techniques	Diva- Scope and responsibility*	Qisda Scope and responsibility*
Analysis of Data	Where appropriate, both Parties shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.	

IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized representatives as of the date first above written.

Qisda Corporation
By:
Name: Peter Chen
Title: Chairman & CEO

Qisda Electronics (Suzhou) Co., Ltd.
By:
Name: Eric Lee
Title: Chairman of Qisda(Suzhou)

DIVA Laboratories, Ltd.
By:
Name: Joe Huang
Title: Chairman