MEDICAL DEVICE QUALITY & TECHNICAL AGREEMENT BETWEEN

PURCHASER:

JAMJOOM MEDICAL INDUSTRIES CO.LTD

AND

SUPPLIER:

VIAMED LIMITED

This document is intended to form the basis for a Supplier Agreement for a medical device manufacturer. The document should be tailored to the specific requirements based on the product or service procured, the capability of the JMI, the capability of the supplier, and the regulatory framework applied to the medical device

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1.0 ADMINISTRATIVE ELEMENTS

1.1 SCOPE

This agreement defines the Quality Agreement between the parties identified below. It defines the commitment both parties make to ensure that their respective products and services satisfy the quality and regulatory requirements called out in this agreement. Both parties agree to cooperate in the success of this agreement.

This agreement does not define the forecasting, ordering, delivery, or pricing requirements for either party.

1.2 Parties to the Agreement

This Quality Agreement is executed between:

Supplier Name	Business Address
VIAMED LIMITED	15 STATION ROAD, CROSS HILLS, KEIGHLEY WEST, YORKSHIRE, UK

Purchaser Name	Business Address
JAMJOOM MEDICAL INDUSTRIES	Jeddah industrial city-Zone 4 Road 409, Sub-street 403, Jeddah 21413- K. S. A. Tel:(012) 6370437 Fax: (012) 6380772

We declare our agreements to provide the goods or services defined below in full conformance with the requirements of this agreement and the supplier should notify the purchaser of changes in the purchased product prior to implementation of any changes that affect the ability of purchased product to meet specified purchase requirements.

1.3 DEFINITIONS & ABBREVIATIONS,

The following terms are included in this agreement.

Complaint: A written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

Concession: Permission to use or release material that does not conform to specified requirements. A concession is frequently called a Use-As-Is (UAI) disposition.

Corrective Action: Action to eliminate the cause of a detected nonconformity or other undesirable situation
IM&TE: Inspection, measuring, and test equipment

Product: Product is the output of a process and includes, but is not limited to, goods, services, software, documentation, and consulting.

Promptly: Unless specified otherwise, promptly means within ten working days.

QMS: Quality Management System

Repair: Action on nonconforming material to make it acceptable for the intended use

Rework: Action on nonconforming material to make it conform to the requirements

RMS: Risk Management System

Scrap: Action on nonconforming material to preclude its originally intended use

Supplier: The Supplier delivers product to the JMI. The term Supplier includes, but is not limited to, contractors, consultants, sister organizations, and parent organizations.

1.4 REFERENCED DOCUMENTS

21 CFR Part 820 Quality System Regulation

GHTF/SG3/N15R8 Implementation of risk management principles and activities within a Quality Management System

GHTF/SG3/N17:2008 Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers

ISO 9001:2015 Quality Management Systems – Requirements

EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

ISO 14971:2019 Medical devices – Application of risk management to medical devices

1.5 PRODUCTS AND SERVICES COVERED BY THIS AGREEMENT

This agreement pertains to the products listed in the table below.

Products covered by this agreement:

Sr. #	Products
1	FLOW SENSOR RERUSABLE

1.6 SITE(S) INVOLVED

The Supplier produces the product at any of the sites listed below. The Supplier ships the product to the JMI from any of the sites listed below.

Supplier Sites Involved in This Quality Agreement:

Supplier Production Site	Supplier Distribution Site
15 STATION ROAD, CROSS HILLS, KEIGHLEY WEST, YORKSHIRE, UK	NA

The JMI receives the product at any of the sites listed below.

JMI Sites Involved in This Quality Agreement:

JMI RECEIVING SITES
Jeddah industrial city-Zone 4 Road 409, Sub-street 403, Jeddah 21413 - K. S. A.

1.7 QUALITY MANAGEMENT SYSTEMS

1.7.1 Quality System Regulation

The Supplier and the Customer shall each maintain a Quality Management System (QMS) that conforms to the requirements of the Quality System Regulation

Should the Supplier determine that a requirement of is not appropriate or not applicable to the product delivered, the Supplier shall notify the Customer within thirty days of making that determination. The list of agreed not appropriate or not applicable requirements is

1.7.2 EN ISO 13485:2016 - MDD DIRECTIVE 93/42/EEC

The Supplier and Customer shall each maintain a Quality Management System (QMS) that conforms to the requirements of EN ISO 13485:2016. & MDD Directive 93/42/EEC

The Supplier shall provide a copy of the QMS certificate, CE Certificate and Declaration conformity according to Directive 93/42/EEC to the JMI.

Should the Supplier determine that a requirement of EN ISO 13485:2016 is not appropriate or not applicable to the product delivered, the Supplier shall notify the JMI within thirty days of making that determination. The list of agreed not appropriate or not applicable requirements.

1.7.3 ISO 14971:2019

The Supplier and the Customer shall each maintain a Risk Management System that conforms to the requirements of ISO 14971:2019. In addition, both the Supplier and the Customer shall integrate the Risk Management System (RMS) into the Quality Management System (QMS) employing the principles in GHTF/SG3/N15R8.

Should the Supplier determine that a requirement of ISO 14971:2019 is not appropriate or not applicable to the product delivered, the Supplier shall notify the Customer within thirty days of

making that determination. The list of agreed not appropriate or not applicable requirements is

1.7.4 OTHER REQUIRED STANDARDS

The Supplier shall produce products in accordance with the requirements of the standards

Should the Supplier determine that a requirement of a listed standard is not appropriate or not applicable to the product delivered, the Supplier shall notify the Customer within thirty days of making that determination.

1.8 TERM OF AGREEMENT

This Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of any product by the Supplier to the JMI, unless the JMI specifically requests an extension of the Agreement. Either party may terminate this Agreement by giving 6 months written notice to the other party.

We declare our agreements to provide the goods or services defined below in full conformance with the requirements of this agreement and the supplier should notify the purchaser of changes in the purchased product prior to implementation of any changes that affect the ability of purchased product to meet specified purchase requirements.

The manufacturer product's records shall be maintained till the product's shelf life

with additional two years.

1.9 ASSIGNMENT

Neither party shall have the right to assign any or all of its rights or obligations under this agreement without the other party's prior written consent, which shall not unreasonably be withheld. The foregoing notwithstanding, prior written consent shall not be required in connection with a merger, consolidation, or a sale of all or substantially all of party's assets to a third party, except if such merger, consolidation or sale is with a competitor of the other party.

2 COMPLIANCE

2.1 SPECIFICATIONS

The Supplier shall be delivered the product as per below defined specifications for the product. This could take many forms including drawings, reference to commercial specifications, identify of brand names, and standards. The specifications may be paper documents, electronic documents or other appropriate media.

The supplier undertakes to deliver product/material in full conformance as per above agreed specification

2.2 SPECIFICATION CHANGES

Changes to specifications are made by mutual agreement between the Supplier and the Customer. In addition to agreement of the change, the Supplier and JMI will determine the effectivity date of the change.

2.3 ACTIVITY BY REGULATORS, NOTIFIED BODIES, OR CERTIFICATION BODIES

The Supplier shall promptly notify the Customer of any inspections, audits, formal visits, etc. of any regulator, notified body, or certification body acting in a formal capacity.

Upon the JMI's request, the Supplier shall disclose the results of any inspections or audits and the associated cause and corrective action.

The Supplier shall promptly notify the JMI of any inspection or audit findings that impact the safety, effectiveness, conformity, or availability of product the Supplier provides to the JMI.

2.4 UNANNOUNCED AUDIT

The supplier shall be ready and allow to JMI's Notified body access to perform an Unannounced audit at their locations. This visit may be without your prior knowledge.

The Supplier shall promptly notify the JMI of any unannounced audit findings that impact the safety, effectiveness, conformity, or availability of product the Supplier provides to the JMI Upon the JMI's request, the Supplier shall disclose the results of unannounced audit findings

and the associated cause and corrective action

2.5 VIGILANCE, ADVERSE EVENT REPORTING

the supplier shall promptly notify the JMI of any adverse event reported, the supplier shall evaluate the INCIDENTs and FIELD SAFETY CORRECTIVE ACTIONS (FSCA) involving MEDICAL DEVICEs, known as the Medical Device Vigilance System.

Upon the JMI's request, the Supplier shall disclose investigation finding, vigilance incident report and field safety corrective action

2.6 THIRD PARTY QUALITY AGREEMENTS

The Supplier shall have a Quality Agreement with Third Party Suppliers used for production, packaging, testing, processing, or release. Upon the JMI's request, the Supplier will provide a copy of the Quality Agreement.

3 MANUFACTURING, PACKAGING, AND LABELING

3.1 ENVIRONMENTAL CONTROL

If environmental conditions could reasonably be expected to have an adverse effect on product quality, the Supplier shall establish and maintain procedures, including maintenance, adjustment, and inspection to adequately control these environmental conditions.

The Supplier shall keep records of these activities and make them available to the JMI upon request.

3.2 PERSONNEL

If contact between personnel and the product could reasonably be expected to have an adverse effect on product quality, the Supplier shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel to adequately control this contact.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.3 EQUIPMENT

The Supplier shall ensure that all equipment used in the manufacturing process for product is appropriately designed, constructed, placed, and installed. The Supplier shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. The Supplier shall keep records of these activities and make them available to the JMI upon request.

3.4 INSPECTION, MEASURING, AND TEST EQUIPMENT

The Supplier shall ensure that all inspection, measuring, and test equipment (IM&TE) used in the manufacturing process for product is suitable for its intended purposes and is capable of producing valid results. Suitability includes limits for accuracy and precision.

The Supplier shall establish and maintain schedules for the calibration, adjustment, cleaning,

and other maintenance of equipment to ensure that manufacturing specifications are met. Calibration standards used for IM&TE shall be traceable to national or international standards.

The Supplier shall keep records of these activities and make them available to the JMI upon request.
The supplier shall ensure that al inspection, measuring, and test equipment (IM&TE) used in the manufacturing process for product is suitable for tis intended purposes an

3.5 LABELING OPERATIONS

The Supplier shall control all labeling and packaging operations to prevent labeling mix-ups.

The Supplier shall keep records of these activities and make them available to the JMI

3.6 PACKAGING OPERATIONS

The Supplier will pack and package the product using the agreed methods or best practices to protect the product from deterioration or damage during processing, storage, handling, and shipment.

The Supplier shall keep records of these activities and make them available to the JMI upon request.

4 STORAGE AND SHIPMENT

4.1 STORAGE

The Supplier shall establish and maintain procedures to control storage areas and stock rooms to prevent mix-ups, damage, deterioration, contamination, or other adverse effects.

The Supplier shall ensure that all products are stored to facilitate proper stock rotation and that product is retrieved from stock using First In, First Out (FIFO) methodology.

4.2 SHIPMENT

The Supplier shall ship products to the JMI using agreed shipping methods to prevent the damage or deterioration of the product.

5 CHANGE CONTROL

5.1 CHANGE REQUESTS

If the Supplier requests to change a document, specification, drawing, etc. under the Customer's control, the Supplier shall document the request including the specific change, the reason for the change, the benefit derived from approving the request, the loss incurred from disapproving the request, and the anticipated lead time before the change is reflected in the product. The JMI shall promptly acknowledge receipt of each change request. The JMI shall make a decision to accept or reject the change within thirty days of acknowledging receipt. For accepted changes, the Supplier and JMI will work together to develop a plan to implement the change.

5.2 DEVIATIONS

If the Supplier needs to deviate from a document, specification, drawing, etc. under the JMI's control, the Supplier shall document the deviation request including the specific deviation, the reason for the deviation, and the period (time, lots, etc.) the deviation will be in effect.

5.3 OTHER CHANGES

The Supplier shall promptly notify the JMI of changes, other than those documented above, in the product or service so the Customer may determine whether the changes may affect the quality of a finished device.

6 NON-CONFORMANCE, CAPA, AND COMPLAINTS

6.1 Disposition of Non-Conforming Material

The Supplier shall segregate, investigate, and disposition all nonconforming material returned by JMI. Concession or repair dispositions require the JMI's written authorization.

If the Supplier requests authorization for a repair or concession disposition, the Supplier shall document the disposition request including the inspection or test conducted, the actual results, and, if applicable, the proposed repair.

6.2 Corrective Action

6.2.1 Supplier Initiated Corrective Action

The Supplier shall initiate corrective action for all detected nonconforming material regardless of disposition. Corrective Action shall include the following steps.

1. Determining the cause(s) of nonconformity
2. Evaluate the need for action to ensure the nonconformity doesn't recur
3. Determine the action needed to prevent recurrence
4. Implement the action needed to prevent recurrence
5. Review the effectiveness of the corrective action

The Supplier shall keep records of these activities and make them available to the JMI upon request.

6.2.2 Initiated Corrective Action

The JMI may initiate corrective action for the Supplier when the JMI identifies a nonconformity after receipt of the Supplier's product.

The Supplier shall initiate corrective action upon receipt of the JMI's initiation. The Supplier's Corrective Action shall include the following steps:

1. Determining the cause(s) of nonconformity
2. Evaluate the need for action to ensure the nonconformity doesn't recur
3. Determine the action needed to prevent recurrence
4. Implement the action needed to prevent recurrence
5. Review the effectiveness of the corrective action

The Supplier shall report the results of the corrective action to the JMI within 15 working days of initiation. When the Corrective Action is not completed within 15 working days, the Supplier shall provide a status report every 5 working days until the corrective action is completed. The Supplier shall keep records of these activities and make them available to the Customer upon request.

7 AUDITS

7.1 Customer Audits of Supplier Facilities

The Supplier shall allow the JMI's authorized representative, to perform audits of the Supplier's facilities, systems, documentation, and other requirements related to this agreement. Audits shall be conducted at mutually agreed dates and times.

The Supplier and JMI will agree upon methods to protect intellectual property such as confidentially agreements, non-disclosure agreements, etc.

7.2 Customer Audit Findings

When conducting audits at the Supplier's location, the Customer will issue an Audit Report within five working days of the audit's conclusion.

The Supplier shall issue a plan to determine the correction, cause, and corrective action for each finding within thirty days of the Audit Report's issue date.

For and on behalf of Jamjoom Medical Industries

Signed: _____

Name : Dr. Ramy Mamdouh

Designation: Sr. Manager-Quality

For and on behalf of VIAMED LIMITED

Signed: _____

Name: S. NIXON

Designation: DIRECTOR

23rd March 2022