Opto Sensors (M) Sdn. Bhd. (Co. No. 307669-T)

QUALITY SYSTEM
SIRIM
CERTIFIED TO MS ISO 9002
Registration No. AR 0732

08 October 2001

Mr. John S. Lamb
Electromedical Equipment,
15 Station Road, Cross Hills,
Keighley, West Yorkshire BD20 7DT,
UK.

Dear John,

Pursuant to the discussion of selecting Viamed as the Authorized EU Representative for OSM's Dolphin and Aristo products herewith attached the Draft Agreement for your review and approvals.

Should there be no problem, please sign both the copies and return to me. I will then have Tom sign these off and a copy will be courier to you for your record retention.

Any amendments needed, please let me know at your earliest.

Sincerely,

K.T. Siow
QA Manager

No. 6, Jalan Angkasa Mas 1, Kawasan Perindustrian Tebrau II, 81100 Johor Bahru, Johor Malaysia .
Tel : + (60) 7-3537008 Fax : + (60) 7-3537010 E-mail : osma@po.jaring.my

This Agreement, by and between Viamed Electro Medical Equipment, an English corporation having a place of business at 15 Station Road, Crosshills Keighley, West Yorkshire, BD20 7DT, United Kingdom ("Viamed") and Opto Sensors (Malaysia) Sdn. Bhd., a Malaysian corporation having a place of business at No.6, Jalan Angkasa Mas 1, Tebrau Industrial Park No.2, 81100 Johor Bahru, Johor, Malaysia ("OSM"),

Witnesseth:

Whereas:

OSM manufactures and sells products intended for medical use under the brand names Aristo™ and Dolphin™ , some of which are or may be available for sale in countries within the European Union and which , therefore, fall under the auspices of the EU Medical Device Directive and,

The EU Medical device Directive mandates that suppliers of medical devices to countries within the EU be located in, or be represented in, the EU and,

Now, therefore, the parties agree:

Viamed will act as the EU representative for Aristo and Dolphin products.

1. Responsibility

It is the responsibility of the Viamed to read, understand, and comply with the responsibilities and requirements.

It is the responsibility of OSM to ensure that the Viamed has read, understands and complies with the responsibilities outlined in this agreement. OSM is responsible for ensuring that the Viamed receives the necessary training to so they are able to understand and meet their responsibilities.

2. Procedure

2.1 Customer Complaints

Viamed:

- Immediately forward to OSM any complaint received from a customer or distributors, as defined in Section 4.

- Facilitate the collection and provide the information necessary for the manufacturer to adequately conduct an investigation of the complaint. The required information includes:
  - Name, address, phone/fax numbers and contact person of distributor reporting the complaint;
  - Device commercial and generic names, catalog number, lot/serial number;
  - Accessories or associated devices used with the subject device;
  - Date complaint reported;
  - Availability of the subject device or same-lot sample device) to be returned to the manufacturer for failure investigation.
  - Health facility name, address, phone/fax numbers, and contact person where the incident occurred;
  - Incident date;

- Incident description; and
- Patient outcome

- When available, forward the subject device to the manufacturer for investigation.
- Forward Customer Reply to the Customer or Distributor.
- Collect additional information from the customer or perform any additional activities as requested by the manufacturer.

2.2 Medical Device Vigilance (Adverse Incidents and Near Incidents)

Viamed:

- Notifies the manufacturer immediately (within 24 hours) of any incident involving the death, serious injury, or near incident (event, malfunction, or other complaint regarding the device or labeling that could lead to death or serious injury), as defined in Section 4.
- Facilities the collection and provide the information necessary for the manufacturer to adequately conduct an investigation of the event and report the information to the Competent Authorities. The required information includes all of the information required for reporting the complaint, with special emphasis on the incident and patient outcomes.
- When available, forward the subject device to the manufacturer for investigation.
- Collect additional information from the customer or perform any additional activities as requested by the manufacturer.
- Submit Medical Device Vigilance Reports and any additionally requested information to the Competent Authorities in which the incidents occurred.
- Inform the manufacturer and forward copies of all communications with the Competent Authorities.
- Maintain copies of Medical Device Vigilance files.

2.3 Product Recall and Advisory Notices

In the event of the initiation of a product recall, Viamed:

- Facilitate communications between the manufacturer and the distributors
- Ensure that the distributors provide the manufacturer or Viamed with an accounting of the subject products included in the recall that remain in the distributors' inventory and have been distributed to customers (catalog number, lot/serial number, and quantities).
- Ensure that the distributors provide the manufacturer or Viamed with a list of customers (name, address, phone/fax numbers, contact person) to whom the subject product was distributed.

- Ensure that the distributors have quarantined any subject product that remains in the distributor's inventory or are retrieved/returned from customers.
- Assist in the translation of advisory notices into the local languages.
- Ensure that the distributors have delivered (by mail, phone, fax, e-mail) advisory notices to the customers.
- Facilitate the service, retrieval/return, and/or destruction of subject product.
- Facilitate the replacement of subject product.
- Communicate with the manufacturer on the progress of the recall activities.
- Notify the Competent Authorities in the countries in which the recall is being performed. Submit reports of the Recall/Advisory Notices and any requested information to the Competent Authorities.
- Inform the manufacturer and forward copies of all communications with the Competent Authorities.
- Perform any addition activities as requested by the manufacturer or EC Representative.
- Maintain Recall/Advisory Notice Files, including records of product accounting, advisory notices, consignee list of customers notified) and service, retrieval/return, and/or destruction of the subject product, and reports and communications with the Competent Authorities.

2.4 Technical Files

Viamed maintains controlled copies of the Technical Files for OSM products.

2.5 Other

Viamed notifies the manufacturer and maintains files of any other communications or requests by the Competent Authorities on the manufacturers behalf.

Viamed performs additional activities as requested by the manufacturer.

3. Definitions

Complaint: A complaint is any indication of the failure of medical product to meet the customer's expectations for quality or to meet performance specifications, which may include any expressed dissatisfaction (written, oral, service all or returned goods) relative to identify, quality, durability, reliability, safety, effectiveness or performance of the device or legibility and accuracy of the product labeling.

Incident: An event which led to the death or serious injury of a patient, user, or other person.

Serious Injury: An injury or illness that is life threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical