AGREEMENT FOR AUTHORIZED REPRESENTATIVE SERVICES

Parties to the Agreement:

Manufacturer: VIAMED LIMITED

15 STATION ROAD, CROSS HILLS, KEIGHLEY
WEST YORKSHIRE, BD20 7DT
United Kingdom

Tel: +44 1535 634542,
Fax: +44 1535 635582

and

Authorized Representative: **JAMJOOM MEDICAL INDUSTRIES CO., LTD**

Road 409, Sub-Street 403, Jeddah Industrial City Zone 4
P.O.Box: 9158, Jeddah 21413, Kingdom of Saudi Arabia
Tel: +966 2 6370437; Fax: +966 2 6380772

A. Definitions

For the purpose of this agreement, the **manufacturer** shall be the natural or legal person responsible for the medical devices he intends to place on the KSA market under his name and for which he already has the necessary authorization to legally place these devices on the market in one of the IMDRF Founding Member jurisdiction.
Furthermore, the definitions specified in the Medical Devices Interim Regulation and its Implementing Rules shall apply.

B. Governing Law

This agreement is subject to the laws of the KSA.

C. Applicable Medical Device Regulation

The Interim Regulation for Medical Devices, issued by the Saudi Food and Drug Authority Board of Directors' Decree number 1-8-1429 dated 27 December 2008, published on 17 April 2009 in Umm AL-QURA Journal year 86 issue No 4249 and its relevant Implementing Rules.

D. Tasks of the Authorized Representative

The authorized representative shall:

a. Represent the manufacturer in its dealings with the SFDA.

b. List each medical device category or generic device group intended to be supplied to the KSA market, as required by Article 8 of the Implementing Rule MDS - IR 3 ***Medical Devices Listing.***

c. Access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with all necessary supporting documentary evidence, required by CHAPTER II of Implementing Rule MDS – IR 6 ***Marketing Authorization***.

d. Cooperate with the SFDA on evaluations and actions taken during market surveillance and/or vigilance procedures described in Implementing Rule MDS - IR7 ***Post-marketing Surveillance***.

e. Make the following information available to the SFDA when so required in relation to its market surveillance activities"

- The marketing authorization issued by the SFDA for the listed medical devices.

- The documentation which was used to demonstrate compliance with the Regulation of the relevant IMDRF founding member jurisdictions.

- The documents approved by the SFDA demonstrating compliance with the specific Saudi provisions referred to in Article 6 of Implementing Rule MDS – IR 6 ***Marketing Authorization.***

f. Inform the SFDA of any adverse events that have occurred outside the KSA but have consequences for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the circumstances and provide information on the corrective action the manufacturer has taken or intends to take.

g. Inform the SFDA of all field safety corrective actions resulting from post-market follow-up investigations performed by the manufacturer for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the reason for the corrective action and provide information on the action the manufacturer has taken or intends to take.

h. Cooperate with parties involved in distribution activities, installation and maintenance of medical devices that have been placed on the KSA market under its mandate.

E. Responsibilities of the Legal Manufacturers Subject to this Agreement

The manufacturer shall:

a. Take all measures necessary to allow the execution of tasks delegated to AR without delay.

b. Make available all necessary information relevant to SFDA regulations for medical devices as and when required.

c. Support to AR for medical device listing

d. Make available all documentary evidence required for Marketing Authorization of devices in KSA

e. Cooperate with AR to fulfill obligations of medical device vigilance activities and post-marketing follow up described in Implementing rule MDS-IR7 on post-marketing surveillance.

F. Medical Devices

The manufacturers designate the authorized representative to act on their behalf for the medical device category indicated in the table below:

	Active Implantable Devices	Non-active Implantable Devices	
√	Anaesthetic and Respiratory Devices	Dental Devices	
	Ophthalmic and optical devices	Electro Mechanical Medical Devices	
	Hospital Hardware	In Vitro Diagnostic Devices	
√	Reusable Devices	Single-use Devices	√
	Assistive Products for Persons with Disability	Diagnostic and Therapeutic Radiation Devices	
	Laboratory Equipment	Healthcare Facility Products and Adaptations	
	Complementary Therapy Devices	Biologically Derived Devices	
	Medical Software	Other Categories	

G. Termination

This agreement may be terminated by the **manufacturer** at any time provided it:

a) Maintains the continuous presence of an authorized representative to represent it within the KSA.

b) Provides the authorized representative with a written notice of termination at least 45 days before the event.

This agreement may be terminated by the **authorized representative** at any time provided it:

a) Undertakes to continue with the tasks specified in D until such time as the manufacturer appoints a licensed alternative to represent it within the KSA.

b) Provides the manufacturer with a written notice of termination at least 90 days before the event.

In the event of the SFDA terminating the authorized representative's license, the authorized representative is expected to continue with the tasks specified in D until such time as the SFDA licenses an alternative authorized representative to represent the manufacturer within the KSA or for 90 days.

H. Other Tasks and Provisions Additional to those Required for Authorized Representative Licensing

Additional tasks of the AR shall:

- Act on behalf of the manufacturer in KSA in relation to the relevant provisions of the Medical Device Interim Regulation and the corresponding implementing rules.

- Take without delay update the provided data/information on MDNR and MDEL, if there any Significant changes or as required by SFDA.

- Renewal or extension of marketing authorization on time

- Establish, document and implement the procedures necessary for performing mandated tasks And also make them available as and when required by SFDA.

- Maintain the traceability of products distributed within KSA

- Ensure that the devices are stored, handled and transported under conditions specified by Manufacturer.

- Post-Marketing responsibility for advertising and marketing material, if any

I. Application Date

This agreement shall enter into force on …21/09/2015……

J. Term of the Agreement

This agreement shall remain in effect for..3.. three years from the date of application indicated in I, or until terminated by either party under the provisions of G

K. Attestation

I, the undersigned, have the authority to accept the delegated tasks to be performed in the KSA, on behalf of the authorized representative named above, and ensure written procedures are applied to the tasks, where appropriate.

Name: Saleh Mohammad Kamal Jamjoom

Signed: .....

Position in organization: General Manager

I, the undersigned, have the authority to agree **on behalf of the legal manufacturer** who is party to this agreement, to take without delay all measures necessary to allow the execution of the tasks delegated to the authorized representative.

I, the undersigned, declare that I have not designated any authorised representative other than that who is party to this agreement to act on my behalf for the medical devices listed in Section F.

Name: DEREK LAMB

Signed: .....

Position in organization: MANAGING DIRECTOR

Date: 2/10/2015