Department of Health, Executive Yuan

The application is in compliance with Good Manufacturing Practice for Medical Devices (Medical device importers/ manufacturers)

Application Reason:

☑ First time application or application for additional product items
☐ Follow-up Original QSD Number：QSD Original approved registration number: Valid date:
☐ Overseas factory investigation
☐ Repeated evaluation Original application number:

Application Date:

1. Applicant

Name of Pharmaceutical Manufacturer: (Chinese)

Address of Pharmaceutical Manufacturer: (Chinese)

License Number of Pharmaceutical Manufacturer:

Person-in-Charge of Pharmaceutical Manufacturer:

Telephone Number: 01535634542 Fax: - 01535 635582

Contact Person: DEREK LAMB Contact Telephone Number: -

2. Basic Information of Factory VIAMED LTD

2.1 Factory Name: VIAMED LTD

2.2 Factory E-mail: info@viamed.co.uk

2.3 Factory Address: 15 Station Rd, Cross Hills Keighley W. YORKS (Country): U.K.

2.4 Person-in-Charge of Factory: DEREK LAMB

2.5 Contact Telephone Number: 01535 634542

2.6 Fax: - 044 1535 635582

* **Instruction: For follow-up applications, please submit applications in accordance with Article 9 of Regulations Governing Inspection of Pharmaceutical Manufacturers three months before the certificate expiry date.**

Applicants please do not fill in here.

Fee receipt stamp of Food and Drug Administration	File receipt stamp of Food and Drug Administration, Department of Health, and application number and application's 2D barcode

File receipt stamp of representative checking institutions

Basic Information of Factory: (Please submit the instruction documents of original factories)

3.1 Year of Factory Establishment: 1976

3.2 Number of Employees: 19

3.3 In addition to the manufacture of medical devices, does the factory also manufacture drugs for mankind, veterinary drugs, biological reagents, radioactive drugs, cosmetics or foods etc?

☑ No ☐ Yes (Please list the product items:)

3.4 Partial manufacturing procedures subject to contract manufacture (Do not fill in here if not applicable)

Items subject to contract manufacture	Contract manufacturers	Address/nation of contract manufacturers	Are you holding ISO13485 or GMP qualification and registration for medical appliances?
			☐ No ☐ Yes Certificate Issuing Department: Certificate Number: Valid Date of Certificate:
			☐ No ☐ Yes Certificate Issuing Department: Certificate Number: Valid Date of Certificate:

(If the space in this form is not enough, please list and describe as an attachment)

3.5 Since the QSD approved registration was obtained, has the original factory had any changes? (This is applicable for follow-up applications for inspection)

☐ Yes (Please choose)

☐	Change of company's dominion	☐	Organizational changes	☐	Quality system changes	☐	Expansion of production line
☐	Other (Please state)						

☑ No changes

3.6 Other important records (eg. obtaining quality system certificate, history of factory name changes, original factories please provide related documents):

(If the space in this form is not enough, please list and describe as an attachment)

3.7 Does the original factory establish the reporting procedures to health administration by the pharmaceutical manufacturers, holding the permit for medical devices, when injury events occur due to the medical devices? (In accordance with regulations of Paragraph 8 of Article 145 of the Standard for the Establishment of Pharmaceutical Factories; please refer to ISO 13485:1996 Sub-Clause 4.14.1/ ISO 13485:2003 Sub-Clause 8.5.1)

☑ Yes Name of procedural document:

Document number: VOP19 Establishing date: 21/3/14

☐ No

3.8 Does the original factory establish the reporting procedures for event explanation (please refer to Paragraph 6 of Article 98 of Standard for the Establishment of Pharmaceutical Factories)? (In accordance with Paragraph 9 of Article 145 of the Standard for the Establishment of Pharmaceutical Factories, please refer to ISO 13485:1996 Sub-Clause 4.14.1/ ISO 13485:2003 Sub-Clause 8.5.1)

☑ Yes Name of procedural document:
Document number: VOP19 VOP10 VM3COP10 Establishing date: 21/3/11

☐ No

3.9 Does the original factory establish the reporting procedures for the recall of products from the market? (In accordance with the related regulations stated in Article 80 of the Pharmaceutical Affairs Act, and principles for drug recall, please refer to ISO 13485:1996 Sub-Clause 4.14.1/ ISO 13485:2003 Sub-Clause 8.5.1)

☑ Yes Name of procedural document:
Document number: VOP19 Establishing date: 21/3/11

☐ No

4. Medical devices in the application for importation:

Item:			
Name of Medical Device (fill in according to the classification of medical devices)	(Chinese) :		
	(English) : VM-2500m VM-2500S		
☐ New product item			
☐ Follow-up product item	Original approved registration number:		
	License number for medical devices related to this product item has been obtained: (for reference only)		
Brief description of product functions and characteristics:	Purpose (Please state):		
	Classification and grading code:		
	Is this product item an implantable or actively implantable medical appliance?	☐ Yes ☑ No	
	Does this product item contain software?	☑ Yes ☐ No	
	Does this product item contain drugs?	☐ Yes ☑ No	
	Sterilization requirement:	☐ Sterilized Sterilization methods: ☐ Ethylene Oxide ☐ Radiation ☐ Moist Heat ☐ Other (Please state) ☐ Sterilization prior to use	
		☐ Sterilization not required	
	Are the ingredients of this product derived from human or animal cells or tissues?	☐ Yes (Origin: ☐ Human ☐ Bovine ☐ Goat) ☐ Swine ☐ Other (Please state) ☑ No	

Note: For the applications for more than one product item, please copy this form and fill in one form for each product. Please fill in the purpose and functions of each product in detail)

5. Examination mode you apply for (note: each application can only apply for one appropriate mode of examination. If you like to change the examination mode, please submit a new application. Blank forms can be left out)

☐ 5.1 Simplified mode of American factories (please fill in the form in appendix 1)

☐ 5.2 Simplified mode of European Union technical cooperation program (or countries/areas that sign for cooperation with Taiwan) (Please fill in the form in appendix 2)

☐ 5.3 Standard QSD mode 1: (For the application that the quality system of original factories was established according to chapters 2 to 21 in volume 4 of the Standard for the Establishment of Pharmaceutical Factories, please fill in the form in appendix 3)

☐ 5.4 Standard QSD mode 2: (For the application that the quality system of original factories was established according to CNS 15013(ISO 13485：2003 version), please fill in the form in appendix 4)

☐ 5.5 Overseas factory investigation mode (please fill in the form in appendix 5)

Please fill in this form by typing in Chinese or English.

I declare the following statements:

☑ 1. The information provided in the application is true.

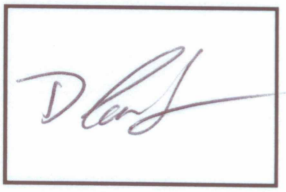
☑ 2. The quality system documents submitted are the latest valid version.

☑ 3. After obtaining approved registration, for any changes of the original factories such as change of address, expansion or addition of more medical devices, the company will submit an application in accordance with the Pharmaceutical Affairs Act and the Regulations Governing Inspection of Pharmaceutical Manufacturers.

If actions are made against the above statements, the company will accept that the application can be rejected or revoked, and bear related legal responsibilities.

Stamp of declarer pharmaceutical company:

Stamp of person in charge of pharmaceutical company:



Appendix 1 Simplified mode of American factories (only applicable for factories in the USA, Puerto Rico, Guam etc)

☐	5.1.1	Establishment Inspection Report as provided by FDA
	☐	According to Exchange of Letters, the Department of Health can obtain it from FDA through TECRO 喊 AIT.
	☐	Manufacturers provide it itself.
	☐	The latest date when FDA conducted on-site inspection at the original factories: (Please submit the statement letter from original factories)
☐	5.1.2	CFG as provided by FDA: ☐ Original copy ☐ Photocopy The original copy is in the application, numbered (Please fill in the application number)
☑	5.1.3	The qualified certificate that is as valid as the GMP standard for medical devices (ISO 13485 certificate) # FM540797
		Certificate issuing institution: BSI UK
		Valid date of the certificate: 11/8/12 -> 11/7/15
☐	5.1.4	The original copy of approved certificate (applicable for follow-up applications)

Appendix 2 Simplified mode of European Union technical cooperation program (or countries/areas that sign for cooperation with Taiwan) (only applicable for factories in countries of European Union, and for the investigation representative institutions only, which participated in "Taiwan-European Union Factory Investigation Report and Technical Cooperation Program", or the countries/areas that have signed the agreement for cooperation).

☐	5.2.1	The institutions of factory investigation and verification of European Union (or the counties/areas that have signed the agreement for cooperation) (Please click): ☑ BSI PS ☐ G-med ☐ mdc ☐ NSAI ☐ TÜV PS ☐ TÜV Rheinland PS ☐ KEMA ☐ DGM ☐ AMTAC ☐ MEDCERT ☐ SGS(UK) ☐ UL (UK) ☐ Other institutions recognized by health administration: Institution name:
☐	5.2.2	The report of the latest date when European Union (or the countries/areas that have signed the agreement for cooperation) conducted on-site inspection at the original factories: date of factory investigation:
☑	5.2.3	The qualified certificate that is as valid as the GMP standard for medical devices (ISO 13485 certificate)
☑		Certificate issuing institution: BSI UK Valid date of the certificate: 11/7/2015
☐	5.2.4	The certificate issued by the highest health administration in the area of the original factories: ☐ Original copy ☐ Photocopy The original copy is in the application, numbered (Please fill in the application number)
☐	5.2.5	The original copy of approved certificate (applicable for follow-up applications)

Appendix 3 Standard QSD mode 1: (For the application that the quality system of original factories was established according to chapters 2 to 21 in volume 4 of the Standard for the Establishment of Pharmaceutical Factories)

☐	5.3.1	The qualified certificate that is as valid as the GMP standard for medical devices			
		Certificate citing standard:	☐ The certificate for manufacture and sale as provided by the highest health administration (applicable for the products made in the USA, and the certificate should clearly state that the manufacturer complies with Current Good Manufacturing Practice for medical devices in the USA)		
			☑ The quality system standard that is equivalent to ISO 13485:1996. Standard name: (Please provide the proof that the standard is equivalent to ISO 13485:1996)		
		Certificate issuing institution:			
		Date of factory investigation:			
☐	5.3.2	Quality system documents			
☐	A.	Quality handbook number:	Issuing date:		Version:
☐	B.	Document catalogue			
☐	C.	Quality system procedural document			
		Requirements of GMP standard		Procedural document number	Version
	☐	Management responsibility (Chapter 2)			
	☐	Quality system (Chapter 3)			
	☐	Contract review (Chapter 4)			
	☐	Design control (Chapter 5)			
	☐	Risk analysis (Chapter 5)			
	☐	Document and data control (Chapter 6)			
	☐	Procurement (Chapter 7)			
	☐	Control of product supply from customers (Chapter 8)			
	☐	Product identification and ascent (Chapter 9)			
	☐	Control of manufacturing procedures (Chapter 10)			
	☐	Examination and test (Chapter 11)			

	☐	Control of facilities for examination and measurement (Chapter 12)		
	☐	Labels for examination and test conditions (Chapter 13)		
	☐	Unqualified product control (Chapter 14)		
	☐	Correction and prevention measures (Chapter 15)		
	☐	Monitoring and reporting back of products in the market (Chapter 15)		
	☐	Procedures of product retrieval from the market (Chapter 15)		
	☐	Reporting of injuries and accidents (Chapter 15)		
	☐	Statement announcement (Chapter 15)		
	☐	Transportation, storage, package protection and goods delivery (Chapter 16)		
	☐	Quality record control (Chapter 17)		
	☐	Internal quality auditing (Chapter 18)		
	☐	Training (Chapter 19)		
	☐	Services (Chapter 20)		
	☐	Statistical technique (Chapter 21)		
☐	5.3.3	Factory floor plan		
☐	5.3.4	Manufacturing operational areas for various types of products (when it is essential, please also label the passageway for operators and goods delivery)		
☐	5.3.5	Main facilities		
☐	5.3.6	Product manufacturing procedures (if there are procedures contracted to other companies, please state the name of the contracted company in accordance with point 3.4)		
☐	5.3.7	The original copy of approved certificate (applicable for follow-up applications)		

Appendix 4 Standard QSD mode 2: (For the application that the quality system of original factories was established according to CNS 15013(ISO 13485：2003 version)

☐	5.4.1	The qualified certificate that is as valid as the GMP standard for medical devices			
☐		Certificate citing standard:	☑ ISO13485：2003		
			☐ The certificate for manufacture and sale as provided by the highest health administration (applicable for the products made in the USA, and the certificate should clearly state that the manufacturer complies with Current Good Manufacturing Practice for medical devices in the USA)		
		Certificate issuing institution:			
		Date of factory investigation:			
☐	5.4.2	Quality system documents			
☐	A.	Quality handbook number:	Issuing date:		Version:
☐	B.	Document catalogue			
☐	C.	Quality system procedural document			
		Requirements (Chapter CNS 15013)		Procedural document number	Version
		Quality management system (Section 4)			
	☐	General requirements (Section 4.1)			
	☐	Document requirements (Sections 4.2.1~4.2.3)			
	☐	Quality record requirements (Section 4.2.4)			
		Responsibility of management level (Section 5)			
	☐	Commitment of management level (Section 5.1)			
	☐	Customer priority (Section 5.2)			
	☐	Quality policy (Section 5.3)			
	☐	Planning (Section 5.4)			
	☐	Duty, limits of authority and communication (Section 5.5)			
	☐	Examination of management level (Section 5.6)			
		Resource management (Section 6)			
	☐	Resource supply (Section 6.1)			

	☐	Human resources (Section 6.2)		
	☐	Fundamental facilities (Section 6.3)		
	☐	Work environment (Section 6.4)		
		Product accomplishment (Section 7)		
	☐	Planning for product accomplishment (Section 7.1)		
	☐	Risk management (Section 7.1)		
	☐	Customer related procedures (Section 7.2)		
	☐	Design and development (Section 7.3)		
	☐	Procurement (Section 7.4)		
	☐	Control of production and services (Section 7.5.1)		
	☐	Product cleaning and contamination control (Section 7.5.1.2.1)		
	☐	Installation activities (Section 7.5.1.2.2)		
	☐	Services (Section 7.5.1.2.3)		
	☐	Special requirements for sterile medical appliances (Section 7.5.1.3)		
	☐	Confirmation of manufacturing and service providing procedures (Section 7.5.2)		
	☐	Efficiency confirmation of sterilization (Section 7.5.2.2)		
	☐	Identification and ascent (Section 7.5.3)		
	☐	Customers' property (Section 7.5.4)		
	☐	Product protection (Section 7.5.5)		
	☐	Control of monitoring and measuring devices (Section 7.6)		
		Measurement, analysis and improvement (Section 8)		
	☐	Feedback (Section 8.2.1)		
	☐	Internal auditing (Section 8.2.2)		
	☐	Procedure monitoring, control and measurement (Section 8.2.3)		
	☐	monitoring, control and measurement (Section 8.2.4)		
	☐	Unqualified product control (Section 8.3)		
	☐	Data analysis (Section 8.4)		
	☐	Improvement (Section 8.5)		

	☐	Reporting of injuries and accidents (Section 8.5.1)		
	☐	Procedures of product retrieval from the market (Section 8.5.1)		
	☐	Statement announcement (Section 8.5.1)		
	☐	Correction measures (Section 8.5.2)		
	☐	Prevention measures (Section 8.5.3)		
☐	5.4.3	Factory floor plan		
☐	5.4.4	Manufacturing operational areas for various types of products (when it is essential, please also label the passageway for operators and goods delivery)		
☐	5.4.5	Main facilities		
☐	5.4.6	Product manufacturing procedures (if there are procedures contracted to other companies, please state the name of the contracted company in accordance with point 20)		
☐	5.4.7	The original copy of approved certificate (applicable for follow-up applications)		

Appendix 5 Overseas factory investigation mode

<table>
<tr><td rowspan="2">☐</td><td rowspan="2">5.5.1</td><td colspan="4">Factory quality handbook:</td></tr>
<tr><td>Number:</td><td>Issuing date:</td><td></td><td>Version:</td></tr>
<tr><td>☐</td><td>5.5.2</td><td colspan="4">Factory floor plan</td></tr>
<tr><td>☐</td><td>5.5.3.</td><td colspan="4">Manufacturing operational areas for various types of products (when it is essential, please also label the passageway for operators and goods delivery)</td></tr>
<tr><td>☐</td><td>5.5.4</td><td colspan="4">Main facilities</td></tr>
<tr><td>☐</td><td>5.5.5</td><td colspan="4">Product manufacturing procedures (if there are procedures contracted to other companies, please state the name of the contracted company in accordance with point 3.4)</td></tr>
<tr><td>☐</td><td>5.5.6</td><td colspan="4">The document stating the legal status of the factory</td></tr>
<tr><td>☐</td><td>5.5.7</td><td colspan="4">A letter of authorization from the original factory (clearly states that the original factory authorizes the pharmaceutical manufacturers in Taiwan to submit an application for oversea factory investigation to the Department of Health)</td></tr>
<tr><td>☐</td><td>5.5.8</td><td colspan="4">Are the medical devices to be imported manufactured at the same factory?
□Yes □No (Please describe about other factories)</td></tr>
<tr><td>☐</td><td>5.5.9</td><td colspan="4">The original copy of approved certificate (applicable for follow-up applications)</td></tr>
</table>