MHRA
Regulating Medicines and Medical Devices

Competent Authority (UK)

Medical Devices Regulations 2002 No. 618, Regulations 19 and 30

Form RG2 – registration of medical devices

For office use only	Date of receipt	

Evidence in support of application checklist					
Authorised representative application Y/N	Designation letter attached Y/N	Applications replacing an existing AR need a cancellation of their contract/agreement from the overseas manufacturer, has the new AR attached it to this registration? Y/N	Details of the device(s) fully provided. Product labelling and instructions for use for custom made active implantable devices ONLY provided Y/N	Legal entity of the business letter attached Y/N	Payment attached Y/N
Further info required documents Y/N	Info / payment/		Proceed with registration Y/N		

PLEASE ONLY COMPLETE THE RELEVANT SECTIONS/BOXES

Part 1: About the registration notification

Please read the accompanying guidance notes prior to completing this form.
Complete in type face or block letters.
The form may be copied if required

1. Enter the date of notification

Day	Month	Year
21	1	15

2. Please indicate if this is the first registration or change of information.
First ☑ Change ☐

If change please provide previous reference number CA

3. Indicate the status of the organisation making this registration notification by ticking the appropriate box.
Manufacturer ☑
Authorised representative ☐
Assembler of System and procedure packs (Regulation 11/ Article 12) ☐
Custom Made Active Implantable Device (please include the instruction for use with the RG2 form) ☐

4. The statement below must be completed by an authorised signatory of the manufacturer, authorised representative, or other organisation responsible for placing the device(s) on the market (see guidance notes).

I, (print full name) DEREK IAIN LAMB

Affirm that the information provided in this notification is accurate and that the Class I devices/custom-made devices/system and procedure packs (Regulation 14/Article 12) (delete as appropriate) covered by this notification meet the provisions of the Regulations which apply to them.

Signed D Lamb Date 21/1/15

Position MANAGING DIRECTOR
Manager/Owner/CEO, CFO, Proprietor etc

Company Name (if you are placing devices on the UK market under your **personal name** please place this information here)
VIAMED LTD

Part 2: manufacturer information

5. Enter the full (a) Company/Personal name, (b) postal address of the UK manufacturer, or the UK authorised representative responsible
(The address information should correlate with details on the packaging and labelling for the devices being registered).

PLEASE NOTE: PO Box, Virtual offices and mail forwarding office addresses are not acceptable – the full postal address of where economic activity is carried out is required we require phone and email contact details and website of manufacturer and or Authorised representative (if one exists)

*Please note in addition to a phone number, a fax/email address is required

UK address

(a) **Company/Manufacturer's name**. If you are not using a company name, **the name of the person** responsible for placing the device on the market is required here.

VIAMED LTD

(b) Address (PO Box address in **not** acceptable)

15 STATION Road
CROSS HILLS
KEIGHLEY
W. YORKS
BD 20 7DT

Telephone* 01535634542 Fax number* or email* dereh.lamb@VIAMED.CO.UK

*You are only required to provide the overseas manufacturers address here, if you are a designated authorised representative (AR)

Manufacturer's address if outside the EU

Place in part (c) Company/Personal name, (d) Postal address for the manufacturer based outside the EU.

(c) Company/Manufacturer's name or person responsible

(d) Address (PO Box address in **not** acceptable)

*Please note in addition to a phone number, a fax/email address is required

(Including international codes)
Telephone* Fax number* or email*

*denotes information which is additional to the requirements of the Directive

Part 3: Payment information

Bank details for payment by bank transfer in pounds sterling or foreign currency
Account name: GBS Re MHRA
Account number: 12314800
Sort code: 08-33-00
Swift code: CITIGB2L
Iban: GB05CITI08330012314800
Branch address:
Citibank N.A.
London Branch
Canary Wharf
London
E14 5LB

Details for making pre-payments to the MHRA using a debit or credit card via our online payment system is located under the following webpage;
http://www.mhra.gov.uk/Aboutus/MakeapaymenttotheMHRA/Debitorcreditcardform/index.htm

Payment method - cheque, credit card, or BACS/CHAPS	Payment ref number (only required for BACS/CHAPS or credit card payments)	Date BACS/CHAPS or credit card payment made
Cheque		

Important note
Registrations submitted and paid via credit/debit card or BACS/CHAPS a copy of the print out or the online verification reference information/page should be provided with the registration form(s).

Part 4: device information

6. *Enter details of notified body approval of quality system for sterilization or measuring function (if relevant to your application)

Notified body identification number:

Covering: N/A

*denotes information which is additional to the requirements of the Directive

Details of the generic codes to use in parts 7, 8 and 9 are given in the guidance part of this form.

Class I Devices complete 7 or 7a

7. Please refer to list of product codes and note generic family group code letter(s). If none appear appropriate enter your generic name(s) at 7a below.

Place generic device code (s) here e.g. H5

H	7			

7a. ONLY Enter your generic name(s) of device, **if you are unable to locate a suitable generic code**. More than one group may be registered providing all other information within the form applies.

Generic description of device here

VERSASTREAM
Airway Adaptor / tubing
Sampling lines

Custom-made device(s) complete 8 or 8a

8. Please refer to list of product codes and note generic family group code letter(s). If none appear appropriate, enter your generic name(s) at 8a below.

Place generic device code (s) here e.g. K1				

8a. Enter your generic name(s) of devices **if you are unable to locate a suitable generic code**. More than one group may be registered providing all the other information within the form applies.

Generic description of device here

System and procedure packs (Regulation 14 / Article12) complete 9 or 9a

9. Please refer to list of product codes and note generic family group code letter(s). If none appear appropriate enter your generic name(s) at 9a below.

Place generic device code (s) here e.g. L5

9a. Enter your generic name(s) of system or procedure packs **if you are unable to locate a suitable generic code.** More than one group may be registered providing all the other information within the form applies.

Sterilization companies (Regulation 14/article 12)

Generic description of device here

10. If you are registering because you sterilize devices for which you are not the manufacturer and place them on the market under your own name, please tick the box. ☐

Send the completed form to:

Registration Scheme Officer
European and Regulatory Affairs (ERA2)
MHRA
Floor 4 yellow zone
151 Buckingham Palace Road
London
SW1W 9SZ

Or via email to: device.registrations@mhra.gsi.gov.uk