PRE-ACQUISITION QUESTIONNAIRE (PAQ Form)

The purpose of this questionnaire is to support the pre-acquisition assessment and approval of proposals to procure Medical Devices and accessories under purchase, exchange, rental, lease, loan, donation or other agreements. Please ensure that all relevant sections have been completed; (questions for which the only available response is 'YES' indicate that this response is a requirement, if the question applies) - and that all supplementary information requested has been provided; (shaded boxes ☐ indicate that supplementary information is required).

Note: The term 'Device', as used here, includes equipment and systems; in the case of systems the requirements below apply both to the individual constituent Devices and to the configured system as a whole. (Accessories within the scope of the return need to be identified under 1(d).)

PART I

to be completed by the device Manufacturer or Authorised Representative

PRODUCT DETAILS:

UDI Device Identifier:		5051826002162
Device Description: (GMDN Code / Group if available)		CT2571 Peripheral nerve electrical stimulators/stimulation systems and associated devices
Type:	Make:	Viamed
	Model:	Microstim DB3
Manufacturer:		Viamed
Supplier:		**Viamed Ltd**
EU Authorised Representative:		

1 a) When was this Model first placed upon the market ? **2006**

b) Is this Model still in production ? NO ☐ YES ☒ if NO, when did production cease ?

c) Any outstanding Field Safety Corrective Actions / Field Safety Notices ? NO ☒ YES ☐ All issued Notices / Alerts attached to this return ? YES ☐

d) Does this return cover a range of Model variants ? NO ☒ YES ☐ If YES, list of Models attached to this return ? YES ☐

e) Does this return cover Accessories ? NO ☒ YES ☐ If YES, list of Accessories attached to this return ? YES ☐

f) Has a Device brochure and specification been attached to this return ? YES ☒

REGULATORY COMPLIANCE:

2 a) Does the Device meet the Essential Requirements of all currently applicable EC Directives ? NO ☐ YES ☒

b) Which EC Directive/s apply ?

Medical Devices Directive ☒ Classification? IIa ← (1, 1-m, 1-s / IIa / IIb / III)

Active Implantable Devices Directive ☐

In-Vitro Diagnostics Medical Device Directive ☐ Category? ← (general / self-test / List-A / List-B)

Other/s ☐

- which Directive/s?

3 a) Is the Device CE-Marked, for its intended use, to all currently applicable EC Directives ? NO ☐ YES ☒

b) - if YES, have the EC Declaration/s of Conformity been attached to this return ? YES ☒

4 If not CE-marked, (or if 'off-label' use is proposed for a CE-marked Device). then -

a) Is this a Medical Device for 'Clinical Investigation' ? NO ☐ YES ☐

- if YES, quote the MHRA 'no objection' reference

- if YES, has a copy of the MHRA's notice of 'no objection' been attached to this return ? YES ☐

b) Is this an In-Vitro Diagnostic Medical Device for 'Performance Evaluation' ? NO ☐ YES ☐

- if YES, has a copy of notification to MHRA been attached ? YES ☐

c) Is this a 'custom-made' Medical Device ? NO ☐ YES ☐

- if YES, name the prescribing Medical Practitioner:

d) - if NO to 3(a), and to 4(a) (b) and (c), then provide justification of the Device's status -

5 a) Which EC conformity assessment route/s have been adopted?

☒ full QA ☐ type examination ☐ product verification ☐ production QA

☐ product QA ☐ unit verification ☐ internal control (self-declaration)

b) Has this included Notified Body conformity assessment ? NO ☐ YES ☐

- Notified Body identification number & name: 0086 **BSI**

c) Is the manufacturer currently certified to any management system Standards ? NO ☐ YES ☒

- which Standard/s ? **13485, 9001** ← (eg: EN-ISO-9001, 13485, 14001, etc.)
- Certification Body: BSI

PRODUCT COMMITMENT:

6 a) To what date is product support for this Model guaranteed ? **1/12/2023**

b) Does this include training; servicing, repair & availability of parts; supply of consumables / accessories ? YES ☐

c) What is the Device warranty period? **12 months** Have warranty details been attached to this return ? YES ☒

d) Does the manufacturer / supplier have a robust system for notification of Device alerts / upgrades to a named hospital representative ? YES ☒

e) What is the recommended working lifetime for this Device? **7 years** ← ('not applicable' for disposable Devices)

f) Have details for end-of-life waste management of the Device been attached to this return ? YES ☒

PRODUCT SUPPORT:

7 a) Can an additional User Manual be provided (electronic format) ? YES ☒

b) Can a Technical Manual be provided (electronic format) ? (Any cost for doing so should be included in the response to 9(a)) NO ☐ YES ☒

c) Is identical equipment normally available as free-of-charge loan in the event of equipment failure ? NO ☒ YES ☐

Commissioning & Deployment

8 a) Has a protocol for post-delivery acceptance testing of Device function and safety been attached to this return ? YES ☒

b) Does the Device have particular installation requirements and / or require ancillary services or other prerequisite arrangements ? NO ☒ YES ☐

- if YES, then have details of all installation requirements been attached to this return ? YES ☐

Technical Support

9 a) Does the manufacturer or an authorised servicing agent provide a maintenance / repair service ? NO ☐ YES ☒

- if YES, then have details of all service contract options been detailed, fully costed and attached to this return ? YES ☒
- where is the servicing facility located ? **Viamed Ltd, Keighley**
- are all servicing staff verifiably trained and competency assessed for the servicing tasks that they perform ? YES ☒
- are qualification / competency records of servicing staff available upon request ? YES ☐

b) Is the servicing organisation currently certified to any management system Standards ? NO ☐ YES ☒

- which Standard/s ? **9001:2008, 13485** ← (eg: EN-ISO-9001, 13485, 17025, etc.)
- Certification Body: **BSI**

c) Do the contract alternatives offered in 9(a) include an option for in-house equipment servicing by hospital staff ? NO ☒ YES ☐

- if YES, have details of the availability of spare / replacement parts to support equipment servicing been attached to this return ? YES ☐
- if YES, have details of information / test equipment / tooling / software required for equipment servicing been attached to this return ? YES ☐

Decontamination

10 a) What level of Device decontamination / reprocessing is required ?

☐ single-use ☒ cleaning ☐ disinfection ☐ sterilisation

b) If not single-use, have validated decontamination protocol/s been attached to this return ? YES ☒

c) For sterilisable Devices, do these instructions meet the requirements of EN-ISO-17664 ? YES ☐

d) Have all requirements for special reprocessing equipment, tools and materials been detailed in the attached information ? YES ☐

e) Have any special post-processing Device storage requirements been detailed in the attached information ? YES ☐

f) Is there a limit to the number of Device reprocessing cycles ? NO ☒ YES ☐ If YES, what is the limit ?

g) Are Devices uniquely identifiable ? NO ☐ YES ☒

h) Is this an implantable Device ? NO ☒ YES ☐

Data Security

11 a) Does the Device store or transmit patient information that will require information governance measures ? NO ☒ YES ☐

- if YES, then have details of information capture / encryption / storage / transmission / deletion been attached to this return ? YES ☐

b) Does the Device interface, by wired or wireless connection, with Information technology (IT) equipment or network systems ? NO ☒ YES ☐

- if YES, then have details of Device IT software / hardware compatibility requirements been attached to this return ? YES ☐
- if YES, then have details of provisions made for Device IT cybersecurity been attached to this return ? YES ☐

Particular Requirements

12 a) Does the Device present particular hazards that require special safety management measures ? NO ☒ YES ☐

(eg: ionising / non-ionising radiation; contamination / infection; hazardous materials; hazardous mechanical / electrical energy; etc.)

- identified hazards:

- if YES, then have details of the nature of identified hazards been attached to this return ? YES ☐

b) Does the Device require particular performance quality assurance measures ? (eg: calibration, qualification, PoCT controls, etc.) NO ☒ YES ☐

- QA measures:

- if YES, then have details of quality assurance requirements been attached to this return ? YES ☐

IMPLEMENTATION SUPPORT:

13 a) Is competency-based user training available from the manufacturer or an authorised provider ? NO ☒ YES ☐

- if YES, have details of user training offered (amount / content / assessment / duration / location / cost / etc.) been attached ? YES ☐

b) Is competency-based technical (equipment servicing) training available from the manufacturer or an authorised provider ? NO ☒ YES ☐

- if YES, have details of technical training offered (amount / content / assessment / duration / location / cost / etc.) been attached ? YES ☐

c) Is competency-based decontamination / reprocessing training available from the manufacturer or an authorised provider ? NO ☒ YES ☐

- if YES, have details of decontamination training offered (amount / content / assessment / duration / location / cost / etc.) been attached ? YES ☐

d) Are qualification / competency records of training providers available upon request ? YES ☐

e) If other additional support facilities are available, (eg: helpdesk, literature, website resources, etc.), have details of these been attached ? YES ☐

DECLARATION:

Please ensure that all necessary supplementary information, (as indicated by shaded boxes ☐ in the Form above) accompanies this return.

1.c)	All issued Field Safety Notices / Alerts	ATTACHED ☐	NOT APPLICABLE ☒
1.d)	List of all Model variants covered by this return	ATTACHED ☐	NOT APPLICABLE ☒
1.e)	List of all Accessories covered by this return	ATTACHED ☐	NOT APPLICABLE ☒
1.f)	Device brochure / specification	ATTACHED ☒	
3.b)	EC Declaration/s of Conformity	ATTACHED ☒	
4.a)	MHRA's notice of 'no objection' for Medical Device 'Clinical Investigation'	ATTACHED ☐	NOT APPLICABLE ☒
4.b)	Notification to MHRA for In-Vitro Diagnostic Medical Device 'Performance Evaluation'	ATTACHED ☐	NOT APPLICABLE ☒
6.c)	Warranty details	ATTACHED ☒	
6.f)	Details for end-of-life waste management of the Device	ATTACHED ☒	
8.a)	Protocol for post-delivery Device acceptance testing	ATTACHED ☒	
8.b)	Details of installation requirements	ATTACHED ☐	NOT APPLICABLE ☒
9.a)	Service support contract options for maintenance / repair	ATTACHED ☒	
9.c)	Availability of spare / replacement parts	ATTACHED ☒	NOT APPLICABLE ☐
	Information / test equipment / tooling / software required for Device servicing	ATTACHED ☐	NOT APPLICABLE ☒
10.b)	Validated decontamination protocol/s	ATTACHED ☒	NOT APPLICABLE ☐
10.d)	Requirements for special reprocessing equipment, tools and materials	ATTACHED ☐	NOT APPLICABLE ☒
10.e)	Details of special post-processing Device storage requirements	ATTACHED ☐	NOT APPLICABLE ☒
11.a)	Details of patient information capture / encryption / storage / transmission / deletion	ATTACHED ☐	NOT APPLICABLE ☒
11.b)	Details of Device IT software / hardware compatibility requirements	ATTACHED ☐	NOT APPLICABLE ☒
	Details of provisions made for Device IT cybersecurity	ATTACHED ☐	NOT APPLICABLE ☒
12.a)	Details of particular hazards that require special safety management	ATTACHED ☐	NOT APPLICABLE ☒
12.b)	Details of particular performance quality assurance measures required	ATTACHED ☒	NOT APPLICABLE ☐
13.a)	Details of user training offered	ATTACHED ☐	NOT APPLICABLE ☒
13.b)	Details of technical training offered	ATTACHED ☐	NOT APPLICABLE ☒
13.c)	Details of decontamination training offered	ATTACHED ☐	NOT APPLICABLE ☒
13.e)	Details of any additional support facilities offered	ATTACHED ☐	NOT APPLICABLE ☒

When reference is made to this Form and its attachments within the process of obtaining the specified product/s, we agree that the purchaser will be entitled to rely upon the contents and that subsequent non-compliance with the statements contained herein will entitle the purchaser to seek redress.

Name:	Catrin Hollings		
Position:	Marketing		
Company:	Viamed Ltd		
Address:	15 Station Road, Cross Hills, Keighley, West Yorkshire, BD20 7DT		
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Signature:	C Hollings	Date:	01/12/16

PART II

for completion by the device Supplier

Previous sections in PART I provided for general Device information; this PART II addendum provides details specific to particular transaction/s for supply of the product:-

TRANSACTIONAL:

14 a) On what basis will the product be supplied, (including Devices for clinical investigation / research) ?

purchase ? ☒ exchange ? ☐ rental/lease ? ☐ loan ? ☐ donation ? ☐

b) For supply by loan or donation, other than Devices for clinical investigation / research -

- has a Department of Health MIA Call-Off Agreement Form been attached ? YES ☐
- does the Supplier have Master Indemnity Agreement (MIA) with the Department of Health (DH) ? * NO ☐ YES ☐
- if YES, then quote DH MIA Register reference number:
- if NO, has an Indemnity Insurance Certificate (for local indemnity agreement with the customer) been attached ? YES ☐

(* Note: unregistered Suppliers are advised to obtain national registration by submission of a MIA Overarching Agreement Form to the DH)

c) For supply by loan or donation of Devices for clinical investigation / research -

- has confirmation of Health Research Authority indemnity approval been attached ? YES ☐

d) Is the particular item to be supplied a pre-used product ? NO ☒ YES ☐

- if YES, has usage and full service history been attached with this return ? YES ☐

Name:	Catrin Hollings		
Position:	Marketing		
Company:	Viamed Ltd		
Address:	15 Station Road, Cross Hills, Keighley, West Yorkshire, BD20 7DT		
Signature:	C Hollings	Date:	01/12/16