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

				be completed by the device Ma	nuiacturei	or Authoris	eu Representative				
PI	ROE	DUCT DETAILS:									
U	DI De	evice Identifier:	505182	6002162							
Device Description: (GMDN Code / Group if available)			CT2571	CT2571 Peripheral nerve electrical stimulators/stimulation systems and associated devices							
		Make:	Viamed								
T'	ype:	Model:	Micros	tim DB3							
М	anuf	acturer:	Viamed								
Sı	upplie	er:	Viamed	Ltd							
		thorised Representative:									
1	a)	When was this Model first	nlaced unon	the market ?					200	6	
•	b)	Is this Model still in produ		the market :	№ П	YES 🖾	if NO, when did production	n cease ?			
	c)	Any outstanding Field Safety Corrective Actions / Field Safety		e Actions / Field Safety Notices		_	All issued Notices / Alerts attached to this		s return ?	YES 🔲	
	d)	Does this return cover a r	-		NO 🖾	YES 🗌	If YES, list of Models attac	hed to this retu	ırn ?	YES 🔲	
	e)	Does this return cover Ac	cessories ?		NO ⊠	YES 🗌	If YES, list of Accessories	attached to this	return?	YES 🔲	
	f)	Has a Device brochure an	d specificatio	n been attached to this return?	?					YES 🛚	
R	EGL	JLATORY COMPLI	ANCE:								
2	a)	Does the Device meet the	Essential Re	quirements of all currently anni	icable EC [Directives ?			№ П	YES 🏻	
2	a) Does the Device meet the Essential Requirements of all currently applicable EC Directives?b) Which EC Directive/s apply?								МО Ц	ILS Z	
	υ,	Medical Devices Directive	, .		(Classification	n? IIa	→	· (1, 1-m, 1-s / II	a / IIb / III)	
		Active Implantable Device	es Directive								
		In-Vitro Diagnostics Medic	cal Device Dir	ective		Categor	y?	← (gener	ral / self-test / Lis	st-A / List-B)	
		Other/s									
		- which Directive/s?									
3	a)	Is the Device CE-Marked,	for its intend	ed use, to all currently applicab	le EC Direc	ctives ?			NO 🗆	YES 🛛	
	b)	- if YES, have the EC Decl	aration/s of C	Conformity been attached to this	s return ?					YES 🛛	
4		If not CE-marked (or if to	ff_lahal' usa i	s proposed for a CE-marked De	wice) then	١ ـ					
4	a)	Is this a Medical Device for		• •	vice). trier	1 -			№ П	YES 🗆	
	u)								110 🗖	123 🗖	
		- 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)			evice for 'Performance Evaluati					NO 🗆		
		- if YES, has a copy of no	tification to M	HRA been attached ?						YES 🔲	
	c)	Is this a 'custom-made' M	edical Device	?					NO 🗌	YES 🗌	
		- if YES, name the prescri	bing 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 asse	ssment route	/s have been adopted?							
		■ full QA		☐ type examination		product v	rerification	production QA	4		
		☐ product QA		☐ unit verification		internal c	ontrol (self-declaration)				
	b)	Has this included Notified	Body conforr	nity assessment ?					NO 🗆	YES 🗌	

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BSI

0086

- Notified Body identification number & name:

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 Is identical equipment normally available as free-of-charge loan in the event of equipment failure? NO YES Commissioning & Deployment		c)	Is the manufacturer cu	rrently certified to any management system Standards?	NO 🗌	YES 🛛		
PRODUCT COMMITMENT:			- which Standard/s?	13485, 9001 ← (eg: EN-ISO	-9001, 13485,	14001, etc.)		
b Does this include training, servicing, regards, a wallability of parts supply of consumables? Accessories? What is the Pookse warranty period? 2			- Certification Body:	BSI				
b Does this include training, servicing, regards, a wallability of parts supply of consumables / accessories? What is the Device warranty period 77 22 abouths Here warranty details been attached to this return 7 YES SQ Obes the manufacturary / supplier have a robust system for notification of Device alersty upgrades to a named hospital representative ? 13 b Does the manufacturary / supplier have a robust system for notification of Device alersty upgrades to a named hospital representative ? 14 size details for end of life waste management of the Device been attached to this return 7 15 c In a Toctricual Manual be provided (electronic format)? 16 c In a Toctricual Manual be provided (electronic format)? 17 c In a Toctricual Manual be provided (electronic format)? 18 c In a Toctricual Manual be provided (electronic format)? 19 c In a Toctricual Manual be provided (electronic format)? 20 c In a Toctricual Manual be provided (electronic format)? 21 c In a Toctricual Manual be provided (electronic format)? 22 c In a Toctricual Manual be provided (electronic format)? 23 c In a Toctricual Manual be provided (electronic format)? 24 c In a Toctricual Manual be provided (electronic format)? 25 c In a Toctricual Manual be provided (electronic format)? 26 c In a Toctricual Manual be provided (electronic format)? 27 c In a Toctricual Manual be provided (electronic format)? 28 c In a Toctricual Manual be provided (electronic format)? 29 c In a Toctricual Manual be provided (electronic format)? 20 c In a Toctricual Manual be provided (electronic format)? 20 c In a Toctricual Manual be provided (electronic format)? 20 c In a Toctricual Manual be provided (electronic format)? 20 c In a Toctricual Manual be provided (electronic format)? 21 c In a Toctricual Manual be provided (electronic format)? 22 c In a manual service formation of provided (electronic formation)? 23 c In a Toctricual Manual be provided (electronic formation)? 24 c In a provided (electronic formation)? 25 c In a toctricual formati				·				
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PRODUCT SUPPORT: 7 a) Can an additional User Manual be provided (electronic format)? (Any cost for doing so should be included in the response to 9(a)) NO						IE3 🖂		
PRODUCT SUPPORT: 7 a) Can an additional User Manual be provided (electronic format)? 8 a) Technical Manual be provided (electronic format)? 9 b) Can a Technical Manual be provided (electronic format)? 10 c) Is identical equipment normally available as free-of-charge loan in the event of equipment failure? 11 c) Is identical equipment normally available as free-of-charge loan in the event of equipment failure? 12 commissioning & Deptoyment 13 commissioning & Deptoyment 14 Eax a protocol for post-delivery acceptance testing of Device function and safety been attached to this return? 15 commissioning & Deptoyment 16 Commissioning & Deptoyment 17 Commissioning & Deptoyment 17 Commissioning & Deptoyment 18 a) Hax a protocol for post-delivery acceptance testing of Device function and safety been attached to this return? 16 So sthe Device have particular installation requirements them attached to this return? 17 Crechnical Support 18 Technical Support 19 A) Does the manufacturer or an authorised servicing agent provide a maintenance / repair service? 18 If YES, then have details of all installation requirements been attached to this return? 19 Crechnical Support 19 A) Does the manufacturer or an authorised servicing agent provide an antached to this return? 19 Crechnical Support 19 Crechnical Sup				<u> </u>		YES 🛛		
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Commissioning & Deployment Commissioning & Deployment					NO 🗆	YES 🖾		
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Technical Support 9 a) Does the manufacturer or an authorised servicing agent provide a maintenance / repair service ? - If YES, then have details of all service contract options been detailed, fully costed and attached to this return ? - YES - Are all servicing staff verifiably trained and competency assessed for the servicing tasks that they perform ? - are all servicing staff verifiably trained and competency assessed for the servicing tasks that they perform ? - are qualification / competency records of servicing staff available upon request ? - b) Is the servicing organisation currently certified to any management system Standards ? - which Standards ? - yes		b)	Does the Device have p	particular installation requirements and / or require ancillary services or other prerequisite arrangements?	NO 🛛			
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d) Have all requirements for special reprocessing equipment, tools and materials been detailed in the attached information? e) Have any special post-processing Device storage requirements been detailed in the attached information? 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 ☐ NO ☑ YES ☐ NO ☑ YES ☐ Data Security Data Security 11 a) Does the Device store or transmit patient information that will require information governance measures? - if YES, then have details of information capture / encryption / storage / transmission / deletion been attached to this return? 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? Particular Requirements Particular Requirements		b)	If not single-use, have	validated decontamination protocol/s been attached to this return?		YES 🛛		
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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? NO YES - if YES, then have details of information capture / encryption / storage / transmission / deletion been attached to this return? 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? Particular Requirements		h)	Is this an implantable I	Device ? NO ☑ YES ☐				
- if YES, then have details of information capture / encryption / storage / transmission / deletion been attached to this return ? 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					Data S	ecurity		
- if YES, then have details of information capture / encryption / storage / transmission / deletion been attached to this return ? 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	11	۵۱	Does the Davice stere	or transmit nationt information that will require information governance measures 2	NO M	VES □		
b) Does the Device interface, by wired or wireless connection, with Information technology (IT) equipment or network systems? - if YES, then have details of Device IT software / hardware compatibility requirements been attached to this return? - if YES, then have details of provisions made for Device IT cybersecurity been attached to this return? - YES - Particular Requirements		a)		•	NO M	_		
- if YES, then have details of Device IT software / hardware compatibility requirements been attached to this return? - if YES, then have details of provisions made for Device IT cybersecurity been attached to this return? Particular Requirements		h)						
- if YES, then have details of provisions made for Device IT cybersecurity been attached to this return? Particular Requirements		D)		•	NO E			
Particular Requirements								
·			- ii its, tileli nave det	ans or provisions made for bevice in cybersecurity been attached to this fetum?		ILO 🛄		
12 a) Does the Device present particular hazards that require special safety management measures?				Particular	Require	ments		
	12	a)	Does the Device preser	nt 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:	the life this color of			YES 🔲						
		YES, then have details of the nature of identified hazards been attached to this return?									
b)	Does the Device require particular performance quality assurance measures.	sures ? (eg: calibration,	qualification, PoC1 controls, etc.)	NO 🛛	YES 🗌						
	- QA measures:- if YES, then have details of quality assurance requirements been atta	ched to this return?			YES 🔲						
LAADLA	CMENTATION CURRENT										
IMPLE	EMENTATION SUPPORT:										
13 a)	Is competency-based user training available from the manufacturer or $% \left(1\right) =\left(1\right) \left(1\right$	an authorised provider	?	NO 🛛	YES 🗌						
	- if YES, have details of user training offered (amount / content / asses	ssment / duration / locat	tion / cost / etc.) been attached?	_	YES 🔲						
b)	Is competency-based technical (equipment servicing) training available			NO 🛛	YES 🗌						
۵)	-	, have details of technical training offered (amount / content / assessment / duration / location / cost / etc.) been attached?									
c)	Is competency-based decontamination / reprocessing training available - if YES, have details of decontamination training offered (amount / co			NO 🛛	YES T						
d)	Are qualification / competency records of training providers available u		ration / location / cost / etc.) been atta	icheu :	YES 🔲						
e)	If other additional support facilities are available, (eg: helpdesk, literati		etc.), have details of these been attach	ned?	YES 🔲						
	ARATION:										
	sure that all necessary supplementary information, (as indicated by sha	ded boxes I in the Fo									
	All issued Field Safety Notices / Alerts			NOT APPLICAT							
	List of all Model variants covered by this return		_	NOT APPLICATION							
	List of all Accessories covered by this return Device brochure / specification		ATTACHED ☐	NOT APPLICAL	OLE M						
3.b)			ATTACHED 🖾								
4.a)			NOT APPLICAT	BLE 🛛							
4.b)	Notification to MHRA for In-Vitro Diagnostic Medical Device 'Performa	nce Evaluation'	ATTACHED □	NOT APPLICA	BLE 🛛						
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)			<u> </u>	NOT APPLICAT	3LE ⊠						
9.a) Service support contract options for maintenance / repair ATTACHED				NOT APPLICAL	n 🗆						
9.c)	 Availability of spare / replacement parts Information / test equipment / tooling / software required for Device 	_	NOT APPLICATION								
10 h	 Validated decontamination protocol/s 	servicing	<u> </u>	NOT APPLICATION							
	 Requirements for special reprocessing equipment, tools and material 	s	<u></u>	NOT APPLICATE							
	Details of special post-processing Device storage requirements		<u> </u>	NOT APPLICAT							
11.a) Details of patient information capture / encryption / storage / transmission / deletion ATTACHEE					BLE 🛛						
11.b)	ATTACHED □	NOT APPLICA	BLE 🛛								
	Details of provisions made for Device IT cybersecurity	ATTACHED □	NOT APPLICA	BLE 🛛							
12.a)	Details of particular hazards that require special safety management		ATTACHED □	NOT APPLICAT	BLE 🛛						
12.b)	Details of particular performance quality assurance measures require	d		NOT APPLICAT							
13.a) Details of user training offered ATTACHE				NOT APPLICA							
	Details of technical training offered		_	NOT APPLICAT							
	Details of decontamination training offered			NOT APPLICAT							
13.e,) Details of any additional support facilities offered		ATTACHED □	NOT APPLICAT	3LE 🔼						
When refe	erence is made to this Form and its attachments within the process of c	obtaining the specified p	roduct/s, we agree that the purchaser	will be entitled	d to rely						
upon the	contents and that subsequent non-compliance with the statements con	tained herein will entitle	the purchaser to seek redress.								
Name:	Catrin Hollings										
Positio	n: Marketing	· ·									
Company: Viamed Ltd											
Addres	s: 15 Station Road, Cross Hills, Keighley, Wes	t Yorkshire, BD20	7DT								
Websit											
Email:	catrin.hollings@viamed.co.uk	Telephone:	01535 634542								
Signatu	ure: 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:-

T	TRANSACTIONAL:										
14	a)	On wha	On what basis will the product be supplied, (including Devices for clinical investigation / research)? purchase?								
	b)	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 🔲			
			he Supplier have Master Indemnity Agreement (MIA) with the Department		DH) ? *	N	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? (* Note: unregistered Suppliers are advised to obtain national registration by submission of a MIA Overarching Agreement Form to 										
	c) For supply by loan or donation of Devices for clinical investigation / research -										
	۹)	- has confirmation of Health Research Authority indemnity approval been attached?									
	d) Is the particular item to be supplied a pre-used product?if YES, has usage and full service history been attached with this return?							YES T			
1	Name: Catrin Hollings										
Position:			Marketing								
Company:			Viamed Ltd								
Address:		SS:	15 Station Road, Cross Hills, Keighley, West Yorkshire, BD20 7DT								
Signature:		ure:	Cfforlings	Date:	01/12/16						