

PRE-ACQUISITION QUESTIONNAIRE (PAQ Form)

The purpose of this questionnaire is to support the pre-acquisition assessment and approval of proposals to procure devices and accessories under purchase, exchange, rental, lease, loan, donation or other agreements. Please ensure that all relevant sections have been completed and that all supplementary information requested has been provided.

(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

b) Which EC Directive's apply? Medical Devices Directive Active Implantable Devices Directive YES In-Vitro Diagnostics Medical Device Directive YES Other/s - which Directive/s? 2 a) Is the device CE-Marked, for its intended use, to all currently applicable Directives? - which Directive/s? 1 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'? - if YES, have the EC Declaration/s of Conformity been attached to this return? 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'? - if YES, has a copy of the MHRA' no objection 'reference number: - if YES, has a copy of notification to MHRA been attached to this return? Is this an In-Vitro Diagnostic Medical Device for 'Performance Evaluation'? - if YES, has a copy of notification to MHRA been attached? - if YES, name the prescribing Medical Device of 'Performance Evaluation'? - if YES, name the prescribing Medical Practitioner: Which EC conformity assessment route/s have been adopted? internal control	who	le.)	,,	1. 1	, ,	,	****					
Product Description: fosce toos recognitionables Type: Make: Ceratherm	NU	ЛН С	CLINICAL ENGINEER	ING REFEI	RENCE NUMBER:							
Machice Ceratherm Ceratherm Ceratherm Ceratherm Make: Ceratherm Make: Ceratherm Make: Ceratherm Make: Geo. 3 Manufacturer: Nufer AG Supplier: Viamed Usined Ceratherm Viamed Ceratherm Viamed Ceratherm Viamed Ceratherm Viamed Ceratherm Viamed Ceratherm Ceratherm Viamed Ceratherm	SU	PPL	LIER REFERENCE NU	MBER:			0310302					
Manufacturer:			1		Cerathern	n 600-3 r	adiant wa	rmer				
Model: 660 3				Cerati	Ceratherm							
Supplier: Viamed EU Authorised Representative*: Viamed (*Manufacture, Supplier, or other) REGULATORY COMPLIANCE: 1 a) Does the device meet the Essential Requirements of all currently applicable EC Directives? Medical Devices Directive Active Implantable Devices Directive YES Classification? IID (1, long, 1+ /fls, /fls	Ту	pe:	Model:	600 3								
EU Authorised Representative*: Viamed	М	anuf	acturer:	Nufer	-							
EU Authorised Representative*: Viamed				Viame								
(* Manufacturer, Supplier, or other) REGULATORY COMPLIANCE: 1 a) Does the device meet the Essential Requirements of all currently applicable EC Directives? 1 b) Which EC Directive's apply? Medical Devices Directive Active Implantable Devices Directive Active Implantable Devices Directive YES Classification? IID -(1, i.e., i.e./i.o/m/cm/cm/cm/cm/cm/cm/cm/cm/cm/cm/cm/cm/c												
b) Does the device meet the Essential Requirements of all currently applicable EC Directives? Mich EC Directive's apply?	_		•		<u>-</u>							
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Other/s			-		ective	i	Category?			neral / self-test	/ List-A / List-B	
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c) Is the manufacturer currently certified to any management system Standards? - which Standard/s? - Certification Body: Description 13485/2012		b)		-	ity assessment?				٦	NO	YES	
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- if YES, indicate cost if this will incur additional charge: 6 a) When was this Model first placed upon the market? 1998			•							NO	1 1	
6 a) When was this Model first placed upon the market?		C)		-	ditional charge:						YES	
	,	,			_							
YES If not, when the production cease?	6			-	e market'?	vec 🖂	If not when d	lid production cases?		1998		
		0)	15 uns iviouer sum in produc			YES	ii not, whell t	na production cease?				

	c) d)			upport for this Model guaranteed? n attached to this return?	YES	What is	the warranty period?	End of 2020		
7	a)	Is competency-b		12 months						
,	a)	- if YES, have d		NO	YES YES					
8	a)	-	-	livery acceptance testing of device function		YES				
	b)	Does the device	-	NO	YES					
0	-)			s of all installation requirements been atta				NO	YES 🔀	
9	a)		oes the manufacturer or an authorised servicing agent provide a maintenance / repair service? f YES, then have details of all service contract options been detailed, costed and attached to this return?						YES YES	
			ere is the servicing facility located? all servicing staff verifiably trained and competency assessed			Cross Hills, West Yorkshire, BD20 7DT for the servicing tasks that they perform?			TES /	
									YES	
	b)	- which Standard	-	on currently certified to any management	system Standards	NO ← (eg: ISO-9001, 1348:	YES			
		- Certification B		IS09001 IS013485/2012 0086	(eg. 150 7001, 1510.	, 17025, etc.				
	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 d		YES X						
				nining facility located? Ability of spare/replacement parts to support		, West Yorkshir icing been attached			YES	
		- have details of		YES						
	d)	Is free-of-charge loan equipment normally available in the event of equipment failure?						NO	YES	
10	a)	Does the manufa	cturer/suj	pplier have a robust system for notification	on of device alerts/	upgrades to a name	d hospital representative?		YES	
DF	ECON	TAMINATIO	N:							
11	a)	Is the device into	ended to b	be processed/reprocessed for decontamina	ation?			NO	YES	
			if YES, then have validated decontamination protocol/s been attached to this return?						YES	
	b)	-	Are special tools required for dismantling/reassembly?						YES	
	c)		f YES, then at what additional cost (if any)? decontamination/reprocessing training available?						YES	
			-	nination training offered (amount/content	/duration/location/	cost/etc.) been attacl	hed to this return?	NO X	YES	
HA	AZAR	RDS:								
12	a)	Does the produc	t present p	particular hazards that require special ma	nagement? (eg: ha	zardous radiation, et	ce.)	NO X	YES	
		- identified								
		- if YES, then ha	ive details	s of the nature of identified hazards been	attached to this ret	urn?			YES	
CC	ONTR	RACTUAL:								
13	a)		_	vice be supplied?	. 1/1 0	1 0				
	b)	•	purchase? exchange? rental/lease? loan? donation? or Supply by loan or donation, does the supplier have a Master Indemnity Agreement (MIA) with the NHS?						YES	
	,		- if YES, then quote NHS MIA reference number:						for donation)	
			if NO, then for supply by loan, has an NHS Form of Indemnity A been completed and attached to this return?						YES	
	c)	- if NO, then for		YES						
	C)	Is the particular item to be supplied a pre-used device? - if YES, has a full usage and service history been attached with this return?							YES YES	
Wh	en refe			and its attachments within the process of catements contained herein will entitle the p			that the purchaser will be	entitled to rely upon the cor	ntents and	
	Name:	<u> </u>	ek Lamb							
P	ositio	n: Mana	Managing Director							
C	Compa	nny: Viar	Viamed Ltd							
Α	Addres	ss: 15 5	Station							
F	Email:	info	info@viamed.co.uk				01535 634542			
Signature:		ure:	Dlamb			Date:	13/12/13			