Nottingham University Hospitals NHS
NHS Trust

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 whole.)

NUH CLINICAL ENGINEERING REFERENCE NUMBER:

SUPPLIER REFERENCE NUMBER: 0310302

Product Description: (GMDN Code / Group if available)		Ceratherm 600-3 radiant warmer
Type:	Make:	Ceratherm
	Model:	600_3
Manufacturer:		Nufer AG
Supplier:		**Viamed**
EU Authorised Representative*:		**Viamed**

(* Manufacturer, Supplier, or other)

REGULATORY COMPLIANCE:

1 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 YES ☒ Classification? IIb ← (1, 1-m, 1-s / IIa / IIb / III)

Active Implantable Devices Directive YES ☐

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

Other/s YES ☐

- which Directive/s?

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

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

3 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 number:

- 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 2(a), and to 3(a) (b) and (c), then provide justification of the device's status -

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

☐ internal control	☐ EC type examination	☐ conformity to type	☐ production QA
☐ product QA	☐ product verification	☐ unit verification	☒ full QA

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

- Notified Body Identification Number: 0123

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

- which Standard/s? **ISO 13485/2012** ← (eg: ISO-9001, 13485, 14001, etc.)

- Certification Body: 0123

PRODUCT SUPPORT:

5 a) Has a product brochure and specification been attached to this return? YES ☒

b) Can an additional User Manual be provided? YES ☒

c) Can a Technical Manual be provided? NO ☐ YES ☒

- if YES, indicate cost if this will incur additional charge: **FOC**

6 a) When was this Model first placed upon the market? **1998**

b) Is this Model still in production? YES ☒ If not, when did production cease?

c) To what date is product support for this Model guaranteed? **End of 2020**

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

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

- if YES, have details of user training offered (amount/content/duration/location/cost/etc.) been attached to this return? YES ☒

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? NO ☐ YES ☒

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

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, costed and attached to this return? YES ☒

- where is the servicing facility located? Cross Hills, West Yorkshire, BD20 7DT

- are all servicing staff verifiably trained and competency assessed for the servicing tasks that they perform? YES ☒

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

- which Standard/s? ISO9001 ISO13485/2012 ← (eg: ISO-9001, 13485, 17025, etc.)

- Certification Body: 0086

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 technical training offered (amount/content/duration/cost/etc.) been attached to this return? YES ☒

- where is the technical training facility located? Cross Hills, West Yorkshire, BD20 7DT

- have details of the availability of spare/replacement parts to support equipment servicing been attached to this return? YES ☒

- have details of information/test equipment/tooling/software required for equipment servicing been attached to this return? YES ☐

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

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

DECONTAMINATION:

11 a) Is the device intended to be processed/reprocessed for decontamination? NO ☐ YES ☒

- if YES, then have validated decontamination protocol/s been attached to this return? YES ☒

b) Are special tools required for dismantling/reassembly? NO ☒ YES ☐

- if YES, then at what additional cost (if any)?

c) Is decontamination/reprocessing training available? NO ☒ YES ☐

- have details of decontamination training offered (amount/content/duration/location/cost/etc.) been attached to this return? YES ☐

HAZARDS:

12 a) Does the product present particular hazards that require special management? (eg: hazardous radiation, etc.) NO ☒ YES ☐

- identified hazards:

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

CONTRACTUAL:

13 a) On what basis will the device be supplied?

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

b) For Supply by loan or donation, does the supplier have a Master Indemnity Agreement (MIA) with the NHS? NO ☐ YES ☐

- if YES, then quote NHS MIA reference number: ← (Ref-A for loan, Ref-B for donation)

- if NO, then for supply by loan, has an NHS Form of Indemnity A been completed and attached to this return? YES ☐

- if NO, then for supply by donation, has an NHS Form of Indemnity B been completed and attached to this return? YES ☐

c) Is the particular item to be supplied a pre-used device? YES ☐

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

DECLARATION:

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

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