PRE-PURCHASE QUESTIONNAIRE

FORM PPQ

This form is intended to supply prospective purchasers with information about equipment being considered for purchase. It is intended principally for pre-purchase information on electrical medical, dental, ophthalmic and laboratory equipment. The form may also be used for other products, including non-electrical items, and to give information prior to equipment being supplied on loan, in which case not all the questions will be relevant. Please ensure all relevant questions are answered.

For issue and completion by purchaser
PPQ Master Reference:

A unique reference (preferably ten characters maximum) must be given by the supplier
Supplier's Reference: CERATHERM

Equipment Description: Radiant Warmer
Country of Origin: Switzerland Manufacturer: Ing. Nufer AG
Supplier: Ing. Nufer AG
Telephone No: 0041 31 958 66 66 Fax No: 0041 31 951 46 73

CE MARKING

1 a) Does the product carry the CE marking? YES [X] NO [ ]

b) If YES, which EC Directive(s):

i) Active Implantable Medical Device Directive (90/385/EEC) YES [ ]

ii) Medical Device Directive (93/42/EEC) YES [X]

If YES, state classification of device: IIb

Identification No of Notified Body, if applicable: 0123

iii) EMC Directive (89/336/EEC) YES [ ]

iv) Low Voltage Directive (73/23/EEC) YES [ ]

v) Other (please specify) YES [ ]

If YES to i) or ii) above, go to question 6.

2. a) Is the product a "custom-made device"? YES [ ] NO [ ]

b) Or a "device intended for clinical investigations"? YES [ ] NO [ ]

If YES, does it comply with the UK Medical Devices Regulations? YES [ ] NO [ ]

QUALITY ASSURANCE

3. Is the manufacturer currently registered under the DH Manufacturer Registration Scheme for this product? YES [ ] NO [ ]

If YES, please give Registration Number:

4. Is the manufacturer currently registered to any other GMP/quality system standard for this product? YES [ ] NO [ ]

If YES, please state standard:

SAFETY STANDARDS

5. For devices not CE marked to 1 b) i) or ii) above, with which safety standard(s) does the equipment comply?

Standard	*Test house*	*Certificate number*	*Date*

SERVICE / SPARES / INSTALLATION

6. Is service/repair information/manual available? YES [X] NO [ ]

If YES, please state current price 0.00 and indicate contents below:

Full circuit diagrams	Yes	Fault finding procedure	No	Preventive maintenance	N/A
Repair information	Yes	Spare parts listing	Yes	List of special tools/test equipment/etc.	N/A

(Please answer YES, NO or N/A)

For Supplier's Reference

7. a) In addition to the service/repair information/manual, will training be required before the purchaser's technical personnel can provide:

(Please answer YES, NO or N/A)

First-line maintenance	No	Calibration	N/A
Planned preventive maintenance	N/A	Repair	No

b) For those indicated by YES above, is the supplier able to provide training for the purchaser's technical personnel? YES ☐ NO ☐

If YES, will this be free of charge ☐ or chargeable? ☐

If NO, please indicate if details of an organisation which is able to provide this training are available on request: YES ☒ NO ☐

8. a) Is the supplier able to provide an 'as required' repair/maintenance service in the UK? YES ☐ NO ☒

b) Is the supplier able to provide a contract repair/maintenance service? YES ☐ NO ☒

If YES, please confirm that details of repair/maintenance contracts are provided on a separate sheet: YES ☐

c) i) Will repairs normally be performed on the purchaser's site? YES ☐ NO ☒

ii) If repairs are performed off-site, where will these be carried out?

Company: Viamed Location: workshop

9. Is the supplier's maintenance organisation currently registered to a quality system standard? YES ☒ NO ☐

If YES, please state standard: ISO 9001

10. Please indicate when the item was first put on the market: 1995

11. For how many years from the date of last manufacture is the supply of spare parts guaranteed? 10 years

12. Please indicate if spare parts will be made available to the purchaser: YES ☒ NO ☐

13. Is installation necessary? YES ☐ NO ☒

If YES, please confirm that details of all services required are given on a separate sheet: YES ☐

DECONTAMINATION

14. Does decontamination require the use of specific equipment? YES ☐ NO ☒

If YES, please state equipment type and parameters of operation (eg. temperature, pressure, etc):

WARRANTY

15. Please confirm that a copy of the warranty is provided on a separate sheet: YES ☒

DECLARATION

When reference is made to this form and its attachments within the process of obtaining the item, we agree that the purchaser will be entitled to rely upon the contents. Subsequent non-compliance with the statements contained herein will entitle the purchaser to seek redress. I am authorised to sign this declaration. I declare that to the best of my knowledge the information given is correct.

Signature (not a copy): Date: 28.1.1999

Name: Dieter Indermühle Position: Product Manager

Company

Address: **Ing. Nufer AG**
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