




## PRE-PURCHASE QUESTIONNAIRE

Produced by:

NHS Supplies, Scottish Healthcare Supplies, Northern Ireland Central Services Agency and Welsh Health Supplies in conjunction with the Association of British Healthcare Industries

This form is intended to supply prospective purchasers with information  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: SUCTION

Equipment Description: SUCTION

Country of Origin: UK

Manufacturer: EAST HEALTHCARE

Supplier: EAST HEALTHCARE/PENLON LIMITED

Telephone No: 01235 547000

Fax No: 01235 547023

### CE MARKING

1. a) Does the product carry the CE marking? YES ☒ NO ☐
- b) If YES, which EC Directive(s):
- i) Active Implantable Medical Devices Directive (90/385/EEC) YES ☐
- ii) Medical Devices Directive (93/42/EEC) YES ☒
- If YES, state classification of device (93/42/EEC Annex D): 2 (a)
- Identification No. of Notified Body, if applicable: 0473
- 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 the 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 provided? YES ☒ NO ☐
- If YES, please state current price: FOC and indicate contents below:
- |                       |     |                         |     |                                          |     |
|-----------------------|-----|-------------------------|-----|------------------------------------------|-----|
| Full circuit diagrams | YES | Fault finding procedure | YES | Preventive maintenance                   | YES |
| Repair information    | YES | Spare parts listing     | YES | List of special tools/test equipment/etc | N/A |

(please answer, YES, NO or N/A)

Name: ALAN GREEN  
 Company: EAST HEALTHCARE/PENLON LIMITED  
 Address: RADLEY ROAD, ABINGDON, OXON OX14 3PH  
 Position: TECHNICAL DIRECTOR  
 Date: 11/07/01

Signature (not a copy): *[Signature]*

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 authorized to sign this declaration. I declare that to the best of my knowledge the information given is correct.

## DECLARATION

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



YES

## WARRANTY

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

Does decontamination require the use of specific equipment?



YES

NO

## DECONTAMINATION

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



YES

NO

12. Please indicate if spare parts will be made available to the purchaser:



YES

NO

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

10 YEARS

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

1990

9. If YES, please state the standard:

EN 46001 / ISO 9001

Is the supplier's maintenance organisation currently registered to a quality system standard?



YES

NO

OXFORD

Location:

EAST HEALTHCARE

Company:

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



YES

NO

Will repairs normally be performed on the purchaser's site?



YES

NO

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



YES

NO

Is the supplier able to provide a contract repair/maintenance service?



YES

NO

Is the supplier able to provide an 'as required' repair/maintenance service in the UK?



YES

NO

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



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



b) For those indicated by YES above, is the supplier able to provide training for the purchaser's technical personnel?



YES

NO

Planned preventative maintenance

NO

Repair

First-line maintenance

NO

Calibration

N/A

SUCTION

For Supplier's Reference:

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)