

PRE-PURCHASE QUESTIONNAIRE

EXTENDED FORM PPQ – June 2003

Produced by NHS Purchasing and Supply Agency, Scottish Healthcare Supplies, Northern Ireland CSA Regional Supplies Service and Welsh Health Supplies in conjunction with the Association of British Healthcare Industries

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:		080212	
Generic Device Type:	Medical Device	Equipment Model:	BSD Foetal Doppler
	China	Manufacturer:	DARAY Limited
Supplier:	DARAY Limited	Telephone No:	0333 321 0971
Fax No:	0333 321 0973	e-mail:	info@daray.com

CE MARKING

1. a) Does the product carry the CE marking? YES NO

b) If YES, to 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 IX) **Class IIb**

 iii) *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) YES

 If YES, is the device: For self-testing? YES Covered by Annex II: List A? YES List B? YES NO

 For ii) and iii) above, Identification No. of Notified Body, if applicable **0120**

 iv) EMC Directive (89/336/EEC or superseding directive) YES

 v) Low Voltage Directive (73/23/EEC) YES N/A

 vi) Other Directive(s) (please specify)

2. a) Is the product a 'custom-made device' (93/42/EEC)? YES NO

b) Is the product intended for 'clinical investigation' (93/42/EEC) or 'performance evaluation' (98/79/EC)? YES NO

 If YES to a) or b) above, does the device comply with the UK Medical Devices Regulations? YES NO

MANAGEMENT SYSTEM STANDARDS

3. a) Is the manufacturer currently registered to any management system standards (eg ISO 9001, ISO 14001, ISO 13485)? YES NO

 If YES, please state the standard(s) and certification body: **ISO 9001:2008, ISO13485:2003 SGS**

b) Is the supplier's service and repair organisation currently registered to any management system standards? YES NO

 If YES, please state the standard(s) and certification body: **ISO 9001:2008 ,ISO 13485:2003 SGS**

SAFETY STANDARDS

4. For products not CE marked to 1 b) I), ii) or iii) above, with which safety standard(s) does the product comply?

Standard	Test House	Certificate Number	Date

SERVICE / SPARES / INSTALLATION

5. Is service/repair information available? YES NO If NOT f.o.c. please state current price Indicate contents below:

(Please state YES, NO or N/A)	Full circuit diagrams	N/A	Fault finding procedure	N/A	Preventative maintenance	N/A
	Repair information	N/A	Spare parts listing	N/A	List of special tools/test equipment/etc	N/A

If YES, please state whether also available on: Disk N/A Website N/A If Web, please state address

6. a) In addition to the service/repair information/manual, will training be required before competent technical personnel can provide:

(Please state YES, NO or N/A)	First-line maintenance	N	Calibration	N
	Planned preventative maintenance	N	Repair	N

b) Is the supplier able to provide this training for the purchaser's or a third party's technical personnel? YES NO

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

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

- c) Is the provision of service/repair information conditional upon completion of training? YES NO
- d) In order to undertake maintenance/repair/calibration, is any special software/test equipment/tooling required? YES NO
If YES, please indicate that details of special software/test equipment/tooling are provided on a separate sheet: YES
7. 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) If repairs are normally performed by the supplier on the purchaser's site, please state typical response time:
ii) If repairs are performed off-site, where will these be carried out?
Company: Location: Typical turnaround time:
iii) Is free of charge loan equipment normally available? YES NO
8. Please state if repair parts will be available to the purchaser's or a third party's suitably trained and equipped personnel: YES NO
If YES, is the supply of repair parts conditional upon acquisition of repair information? YES Or training? YES NO
9. Please indicate when this model was first placed on the market:
10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?
b) Is the product still in current production? YES NO If NO, indicate year of last manufacture:
11. Is installation necessary? YES NO
If YES, please confirm that details of all services required are provided on a separate sheet: YES
12. Will software upgrades be notified? N/A YES NO

IONISING RADIATION

13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation? YES NO

DECONTAMINATION / REPROCESSING

14. a) i) Will the item be reprocessed (cleaned, disinfected, sterilised)? YES NO If NO, go to Question 15.
ii) If YES, is the item intended to be: Non-sterile for single use Sterilized Disinfected Other
iii) Is there a recommended maximum number of uses? YES NO If YES, please state:
iv) Are decontamination/reprocessing instructions supplied? YES NO
v) Are instructions available for safe disposal? YES NO
- b) i) Is manual cleaning the only cleaning method specified before further reprocessing? YES NO
ii) What is the maximum temperature that can be used for thermal disinfection? Temp:
iii) Are there any restrictions on detergent/disinfectant types? YES NO If YES, please state:
iv) Can the item withstand autoclaving at 137 °C for 3 mins? YES NO
v) Is the item compatible with other sterilization methods? YES NO If YES, please state:
vi) Does reprocessing require the use of specified equipment? YES NO
If YES, please state equipment type (eg containers, processors, etc) and, where appropriate, parameters of operation (eg temp, pressure, etc):
- c) i) Are tools required to aid dismantling/reassembly, or are lubricants required? YES NO
ii) If YES, are they supplied with the device or available optionally? Supplied Optional Neither
- d) Is decontamination/reprocessing training available? YES NO If YES will this be: Free of charge? Chargeable?
- e) Are reprocessing instructions available on the Web? YES NO If YES, please state address:

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 and subsequent non-compliance with the statements contained herein will entitle the purchaser to seek redress.

Name:	Julie Thomas	Position:	Quality Manager	
Company/Address:	Daray Limited Marquis Drive, Moira. Derbyshire. DE12 6EJ		Date:	14 th October 2010