



VIAMED

15, STATION ROAD, CROSS HILLS,
KEIGHLEY, WEST YORKSHIRE,
BD20 7DT

Telephone Cross Hills (0535) 34542
Telex 557061 (Linkup G)

Your ref: SEV/00/05/05/
Our ref: TCOT/2409

8th February '88

Dear Mr Judge.

Please find enclosed the MLQ2 form as requested by G.Arnold.

Yours sincerely

Stephen Nixon.

With Compliments

Please return this form when completed to:

Gordon Judge
Room 616
DHSS Supplies Technology Division
14 Russell Square
LONDON WC1B 5EP

PRODUCT: VIAMED THERMACOT TC400 Mk1

I have arranged for a sample of the above equipment to be supplied by us to the Electromedical Laboratory, BSI Test House, Hemel Hempstead, for assessment of its compliance with BS 5724 Part 1.

The date arranged is

15th March '88

I understand that the work will be charged to DHSS Scientific & Technical Branch and that we shall receive a copy of the BSI Report in due course.

Signed.....

Date.....

7th March '88

Standard Questionnaire for the supply of Electrically Operated Medical Equipment and Hospital or Dental or Ophthalmic Laboratory Equipment.

Product Information: MLQ2

For Health Authority use.

Please refer to guidance notes MLQ3 before completing this form.

Please enter YES, NO or N/A (Not Applicable) in each box except where otherwise indicated.

Supplier	VIA MED
Product type	INFANT RADIANT WARMER
Model No.	THERMACOT TC 400 MK I
Manufacturer	APPLEYARD AND SONS
Country of Origin	BRITAIN

Indicate whether the equipment is medical, dental, ophthalmic, hospital laboratory, dental laboratory or ophthalmic laboratory equipment.

MEDICAL

QUALITY ASSURANCE (Medical, dental & dental laboratory equipment only).

- 1 Is the manufacturer of this product registered with the DHSS as complying with the Guide to Good Manufacturing Practice for Medical Equipment?

NO

If yes, give the registration number

N/A.

EQUIPMENT STANDARDS

Medical and Dental Equipment

- 2

(a) Does the equipment comply with BS 5724 Part 1?

YES
- (b) If the answer to 2(a) is 'NO' indicate in the box that a list of points of variance is attached.

N/A
- (c) Has the relevant section of BS 5724 Part 2 been published? If so put the Part 2 number in the box.

NO
- (d) Does the equipment comply with the Part 2 specified in 2(c)?

N/A
- (e) If the answer to 2(d) is 'NO' indicate in the box that a list of points of variance is attached.

N/A

Hospital and Dental Laboratory Equipment

- 3

(a) Does the equipment comply with the Electrical Safety Code for Hospital Laboratory Equipment (ESCHLE)?

N/A
- (b) If the answer to 3(a) is 'NO' indicate in the box that a list of points of variance is attached.

N/A

All Equipment

- 4

(a) List below any British or International Standards (other than those referred to in 2 and 3) applying particularly to this equipment and indicate in the boxes whether or not the equipment complies.
- (i).....

N/A
- (ii).....

N/A
- (b) List below the Standards indicated by the Health Authority in MLQ1, if different from those listed in 4(a), and indicate in the boxes whether or not the equipment complies.
- (i).....

N/A
- (ii).....

N/A
- (c) If any answer in 4(a) or 4(b) is 'NO' indicate in the box that a list of points of variance is attached.

N/A
- 5

Please provide information on equipment type-testing carried out for any Standards referred to in 2(a), 2(c), 3(a), 4(a) or 4(b).

Tested by	Standard	Passed Yes/No	Date

RATINGS, MARKINGS AND DOCUMENTATION

- 6

(a) Is the equipment correctly rated for connection to the UK supply mains?

YES
- (b) Are all written equipment markings, labels and documentation in English?

YES

RADIO FREQUENCY INTERFERENCE

- 7

Does the equipment comply with the requirements of the relevant Standards detailed in the Guidance Notes? If not please give details on a separate sheet..

YES

CLEANING, DISINFECTION AND STERILIZATION

- 8 (a) Are there parts of the equipment which by their nature and function must be cleaned and disinfected or sterilized before use? No
- (b) If the answer to 8(a) is 'YES' please specify the methods of cleaning and sterilization. See Guidance Notes.

Attach a separate sheet if more room is needed

MAINTENANCE

- 9 (a) Is a clear and legible maintenance manual available (including, for example, circuit diagrams and descriptions, component lists, and fault finding procedures)? YES
- (b) If 'YES' state the cost, if any, of
- (i) the first copy £ FOC
- (ii) additional copies £ FOC
- 10 (a) Indicate in the box that a list of the recommended preventive maintenance tasks, if any, and intervals is attached. YES
- (b) Are you able to provide on a contractual basis:
- (i) the preventive maintenance specified at (a)? YES
- (ii) repair? YES
- (c) Indicate in the box that details (including contract conditions) and current annual cost of such a contract are attached. YES
- (d) Indicate in the box that details of non-contract maintenance and repair services are attached. YES
- 11 Are you able to offer a course of maintenance instruction, if appropriate, on the equipment to enable local Health Authority maintenance staff to:
- (i) provide "first-line" maintenance? YES
- (ii) provide a complete maintenance service? YES
- 12 (a) Are qualified staff normally available by phone to deal with problems which occur? YES
- (b) If 'YES', give the appropriate telephone number. 0535-34542

ACCESSORIES, SPARES, REPLACEMENT PARTS AND CONSUMABLES

13 (a) Are there accessories or consumables supplied as sterile for single use?

NO

(b) Is the manufacturer of these products registered with the DHSS as complying with the Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products, 1981?

N/A

If 'YES', give the registration number.

N/A.

14 (a) Is a list of accessories, recommended spares, replacement parts and consumables available, with prices?

YES

TO FOLLOW

(b) Are there lists of recommended spare parts in the maintenance manual?

YES

TO FOLLOW

15 For what period after delivery of the equipment do you undertake to maintain a supply of specialised spare parts?

7 years

16 Will all spares and replacement parts, together with the requisite information, be made readily available for use and fitting by the purchaser

YES

WARRANTY

17 Please attach copies of the warranty for the equipment, showing all relevant terms and conditions.

DECLARATION

Before signing, see Important Notes in the Guidance Notes: Form MLQ3.

I am authorised to sign this declaration. I have made all reasonable enquiries and to the best of my knowledge and belief the information given herein is correct.

Signature

J. S. Lamb

(Not a photo-copy)

Name (please print)

J. S. LAMB

Position in Company

MANAGING DIRECTOR

Date

7th FEBRUARY '88