

**T h e r m o
c o n t o u r[®]**



Regulatory



Barrington Healthcare Products Ltd.
c/o Michael B Allaway
Chief Executive
51 Queen Anne Street
London
W1M 9FA
UK

Your Ref:
Our Ref: CA 000081
Direct Line: (0)20 7972 8250
Direct Fax: (0)20 7972 8112

15 May 1995

Dear Sir,

**MEDICAL DEVICES REGULATIONS 1994: REGULATION 14
Registration of Persons Placing Medical Devices on the Market**

Thank you for informing the Competent Authority of the company's details and for supplying the medical device information. Your registration has been recorded on the understanding that:---

For Manufacturers of Class I medical devices, Assemblers, and Sterilisers

You are now operating under the Medical Devices Directive and the 1994 Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products and labelling them as such.

The information you provided has been recorded against the reference number shown at the top of this letter. Please use this in all future correspondence and communications.

This acknowledgement includes a record made from the information you supplied. Please check and inform us of any incorrect details. In cases where no generic code names were used, names, other than those you provide, may have been recorded. In these cases please consider if the names used would cover your devices. Any changes we have made are intended to establish an acceptable standard terminology for data reference purposes only. Please inform us if we have omitted any range of devices that you notified.

From time to time, the coding of devices will be updated, if any changes are made to your records, we will write and inform you.

Please remember to inform us of any changes to:

- the company information
- additional range of devices
- discontinuation of a range of devices.

Please use RG2, the Registration form, to tell us about any of these changes.

Thank you for registering, and please check the following information:

Class I Devices:

***Allergen Resistant Bedding
Hospital Beds And Patient Positioning Aids
Pressure Relief Devices And Accessories***

Custom Made Devices:

None

Products Covered By Article 12:

None

Should you have any queries regarding your registration please contact Ms Amanda Davis on the telephone number given at the top of this letter.

Yours sincerely



Mr Paul Stonebrook



DECLARATION OF CONFORMITY

We, the offerer:

Barrington Healthcare International Limited
acknowledge our sole responsibility, that the product:

Kind of equipment: Medical Devices
Type designation: Mattresses and Seat Cushions
Product name: Thermo Contour

in accordance with MHRA Directive 93/42/EEC and Article 14(1) of the Directive,
is in compliance with the following norm(s) or document(s):

Medical Device: Class 1
Certificate/report no.: CA 000081 - 1995

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Quality Assurance

All products are manufactured according to
quality assurance standard ISO 13485 - 2003 rules
and are inspected before leaving the factory.

Michael B. Ataway
Managing Director