



Safeguarding Public Health

Ms Joyce Dean
Cremascoli Fry Ortho Ltd.
Unit 17, Goldsworth Park Trading Estate,
Woking,
Surrey.

Our Ref: CA 004951
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GU21 3BA

3 March 1999

Dear Ms Dean,

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

Thank you for informing the Competent Authority of the details of Ruhof Corporation of the USA, for whom you are acting as authorised representative, 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 or labelling them as such.

For Manufacturers of Custom-made devices

You are ready to claim compliance with the Directive and Regulations and are manufacturing custom-made devices in accordance with their requirements.

If you are not yet complying with the Regulations

You should inform us so that we can remove your registration. The transitional period applies until 13 June 1998, when you believe that you meet the requirements of the Regulations, please re-apply for registration.

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

Endoscopes/Endoscopic Instruments And Accessories

Laryngoscopes/Otoscopes And Accessories

Surgical Instrument Accessories

This registration covers the products Endozime, Endozime AW, Endozime AW Plus, Protozime, Orthozime, Lapcholyzime, Liquiclean H, Surgistain, Premixslip, Surgislip and Rinse Aid.

Please note that B.I.P., F.O.E., A.C.T.S. and DeLyme have not registered as in our opinion these are not medical devices and hence do not fall within the provisions of the Medical Devices Regulations. We do not consider general cleaning products, odour reducing products or autoclave/washer disinfectant/boil tank cleaning products (accessory to an accessory) to have a medical purpose as defined in the Medical Devices Directive 93/42/EEC.

Yours sincerely



Ms Amanda Davis

(on behalf of the Competent Authority (UK))