MHRA
Safeguarding public health

Medicines and Healthcare products Regulatory Agency

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Mr Markland
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28 Trinity Road
Nailsea,
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24 May 2005

Dear Mr Markland

I am writing with regards to your emails dated 11, 19 and 29 April 2005, in which you request confirmation from the MHRA that medical devices manufactured by DameTech Corp can be legally sold within the EU.

In our correspondence, you explained that RMS act as the Authorised Representative for DameTech, who wish to place their products on the Egyptian market. The products are currently CE marked under the Medical Devices Directive, however the Egyptian authorities require a letter from an official body within Europe confirming that DameTech Corp can legally sell these products within the EU. In support of the CE marking, you have provided me with copies of the EC Design Examination and Annex II Certificates produced by the Notified Body DQS GmbH.

I can confirm that the certificates that you have shown me appear to be appropriate for supporting the CE marking of the products listed as surgical instruments and absorbable and non-absorbable surgical sutures. It would therefore appear to be appropriate for these products to be sold within the EU.

I hope that this letter is sufficient for your requirements, and I apologise for the time that this has taken.

Yours sincerely

D. Rogers

Daniella Rogers
(on behalf of the UK Competent Authority)