ATTN: JOHN LAMB

(PAPERPORT)

**Steventon Richard (RLZ) MES**

**From:** Walt.Odowd@mhra.gsi.gov.uk
**Sent:** 23 April 2003 10:27
**To:** Steventon Richard (RLZ) MES
**Subject:** Re: Viamed nerve stimulator

You forwarded a colleagues (P.G. Smith, Royal Shrewsbury Hospital) concerns regarding this stimulator to MHRA on 22/04/2003.

The second amendment to the present edition of IEC 60601-1 addresses this point [IEC 60601-1, subclause 56.3c]. It precludes such connectors from compliance.

Standards remain voluntary under the CE marking scheme, however a manufacturer is required to take the hazards raised into account as part of the Risk Analysis for a device. This particular device has been in use since 1985 according to the Viamed website, during which time we have had no reported problems. Since a user would be looking to plug these pins into a box rather than a cable, it is unlikely that an issue will arise. Our previous advice concerned ECG connections (i.e., connection to a cable).

In the USA, the FDA have made compliance with this IEC clause mandatory due to their unfortunate experiences with such connectors; an experience not documented in the UK. [ See http://www.fda.gov/cdrh/comp/fr0509af.html]

I hope that this addresses your concerns but please feel free to contact me directly if I can be of further assistance.

Sincerely,

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IMPORTANT NOTE: On the first of April 2003, the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA) merged to form the new Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health. For more information, visit our website at www.mhra.gov.uk

We have had a few problems with the new e-mail addresses bouncing. If your reply bounces back please re-try but with the mhra replaced by doh in the email address (both will work in parallel for the near future).



file in Risk Assessment