MEDICAL DEVICES AGENCY

Safeguarding Public Health

John S Lamb, Managing Director
Viamed Limited
15 Station Road
Cross Hills
Keighley
West Yorkshie BD20 7DT

Your Ref.:
Our Ref.: E/2002/0538
Direct Line: 020 7972 8235
Direct Fax : 020 7972 8112
E- Mail : Tore.Johansen@doh.gsi.gov.uk

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Dear Mr Lamb,

With reference to your enquiry to Jeff Ali at the MDA of 18 July, we can provide you with the following classification advice, based on the information that you have provided:

The need to separately CE-mark and classify the cot lid only arises if it is sold as a separate item or optional accessory. An accessory is considered as a Medical Device in its own right. If it is not sold separately, it is a component part of the basinet, and the combination is classified as one device.

Assuming you intent to put the cot lid on the market as a separate device, we agree with your opinion that it will fall into Class I in accordance with Annex IX Rule 1 of the Medical Devices Directive. While Class I indicates a relatively low risk device, you are no doubt aware that manufacturers are still obliged to comply with design requirements and other provisions as outlined in Annex VII of the MDD.

For your information, I have added some useful website references below.

The Medical Devices Agency (MDA) is responsible for the enforcement of the Medical Devices Regulations 2002. To assist manufacturers we are willing to give any help and advice we can. However, any views given by us on the interpretation of the Regulations represent our best judgement at the time based on the information available. It is not, however, meant to be a definitive statement of law; that can only be given by the Courts. Accordingly we would always advise you to seek the views of your own professional advisors.

I hope this information is of some help to you.

Yours sincerely

Tore Johansen
Regulatory Affairs Specialist

References:

(1) Directives (text and information):
http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist.html

(2) MDA website (regulatory publications):
http://www.medical-devices.gov.uk/mdawebsitev2.ns4/webvwRegulatoryPublications

(3) MEDDEV guidance documents (including classification guidance):
http://europa.eu.int/comm/enterprise/medical_devices/guidelinesmed/baseguidelines.htm