

Safeguarding public health

The MHRA logo is a blue oval with the letters 'MHRA' in white, bold, sans-serif font.

Mr Martin Battye
Kirton Health Care
23 Rookwood Way
Haverhill
Suffolk CB9 8PA
E-mail: martinbattye@kirtonhealthcare.co.uk
CC : markfowkes@kirtonhealthcare.co.uk

Date: 4th August 2010

MHRA Ref: E/2010/0846

Dear Mr Battye,


Reference our telecons of 3rd and 4th August concerning the design bugs out wheeled commode and whether or not this product would come within the remit of the medical device regulations and therefore require CE marking. You advised that the regulatory status of the product has been questioned and that the product is not currently CE marked as a medical device.

Non-wheeled commodes and toilet seat risers are not considered to be medical devices as their primary intended purpose is toiletry and not medical, they are regarded as aids to daily living. The question that has arisen is therefore whether or not the product would be a medical device because it has wheels.

MHRA is of the view that although this commode has wheels, this does not alter the fact that the primary intended purpose for the product is a toiletry one. We therefore consider that the design bugs out wheeled commode does not come within the remit of the medical device regulations and therefore does not require to be CE marked.

Please note that whilst we are willing to give any help and advice we can, any views given by us on the interpretation of the Medical Device Regulations represent our best judgement at the time, based on the information available. Such views are not meant to be a definitive statement of law, which may only be given by the Courts. Accordingly we would always advise you to seek the views of your own professional advisors.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'C Headley', written in a cursive style.

Mrs Clare Headley
Regulatory Affairs Specialist
Direct Tel: 0207 084 3386
Fax: 0207 084 3112
E-mail: clare.headley@mhra.gsi.gov.uk