Subject: E/2010/0197
Date: Fri, 12 Mar 2010 10:13:05 +0000
From: Dhruti.Patel@mhra.gsi.gov.uk
To: sshakoh@hotmail.com

Dear Dr Shakoh,
Thank you for your enquiry to the MHRA dated 12 February 2010 regarding importing Haemodialysis concentrates to the UK
A product can be defined as a Medical Device if it complies with the definition of a Medical Device under the Medical Devices Directive (MDD) 93/42/EEC Article 1 Clause 2a. Therefore in order to be classified a medical device, a product must be *intended to provide or assist with the diagnosis, monitoring, prevention or treatment of a medical condition*. This will not only depend on the device itself, but also on the claims made by the manufacturer for its intended use in the accompanying documentation (Article 3 annex I).
Haemodialysis concentrates are regarded as Class IIb Medical Devices in accordance to Rule 3 in Annex IX of the Medical Devices Directive 93/42/EEC. From the information provided in your email Renacon intend on placing Haemodialysis concentrates on the UK Market. SGS have been appointed as your Notified Body and the concentrates have been CE Marked with the four digit Notified Body number appearing next to the CE Mark on the labelling, packaging and instructions for use. Furthermore an Authorised Representative within the UK has also been appointed.
As Renacon have a valid CE Certificate the Haemodialysis concentrates may be placed on the UK and European Market. However please note that the labelling and instructions for use must be provided in English. Please note registration with the MHRA will not be required.
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 definitive statements of the law, which may only be given by the Courts. Accordingly, we would always advise enquirers to seek the views of their own professional advisors.
Kind regards

Dhruti Patel
Regulatory Affairs Specialist (Devices)
Medicines and Healthcare Products Regulatory Agency
Room 8/2-A05
Market Towers
1 Nine Elms Lane
London SW8 5NQ
Tel: 0207 084 3194