EC Certificate Full Quality Assurance System: Certificate GB07/73231

The management system of

Renacon Pharma (Private) Limited

18 - K.m. Ferozepur Road, Opp Nishtar Colony, Lahore, Pakistan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Haemodialysis Concentrates

RENACARB (Part A: Solution; Part B: Powder);
RENACIT (Citrate Concentrate: Powder);
RENACIT –S (Citrate Concentrate: Part A: Solution; Part B: Powder)
RENACART (Bicarbonate Cartridge);
RENABAG (Bicarbonate Bag);
RENAPULV (Powder Concentrate);
RENAPULV-N (Powder Concentrate)
RENACATE (Acetate Concentrate Solution);
RENALACT (Lactate Concentrate)

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 16 April 2014 until 15 October 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 October 2016
Issue 10. Certified since 15 October 2007

Certification is based on reports numbered GB/PI 216279

Authorised by

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