EC Certificate Full Quality Assurance System: Certificate PK19/818842595

The management system of

Renacon Pharma 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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 15 October 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 15 October 2007
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered PK/LHR 216279

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Renacon Pharma Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

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)

Blue Sky Renal Concentrate® Concentrate Powder, Part A: Powder, Part B: Powder, Part C: Solution, for Bicarbonate Haemodialysis
Hemosate PW® Concentrate Solution & Powder, Part A: Powder, Part B: Powder, Part C: Solution, for Bicarbonate Haemodialysis
Hemosate CT® Concentrate Powder, Part A: Powder, Part B: Powder, for Bicarbonate Haemodialysis
Hemocart® Concentrate Powder Only, Part B for Bicarbonate Haemodialysis
HemoBag® Concentrate Powder Only, Part B for BicarbonateHaemodialysis
Hemosate 400® Concentrate Solution & Powder, Part A: Solution, Part B: Powder, for Bicarbonate Haemodialysis
Hemosate 300® Concentrate Solution Part B: Solution, for Bicarbonate Haemodialysis

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.