EC Certificate Full Quality Assurance System: KR02/56815

The management system of

HUNIZ Co., Ltd.

22, Noksansandan 165-ro, Gangseo-gu, Busan 618-817, Korea

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 23 April 2013 until 23 December 2016 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 December 2014
Issue 14. Certified since 20 September 2002

Certification is based on reports numbered WW/PCI 208135

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
SGS United Kingdom Ltd Systems & Services Certification
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SGS CE 01 0311 M2

HUNIZ Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 14

Detailed scope

Hemoclean RP Dialyser Reprocessing Solution;

Hemoclean Hemodiálisis units Cleaning and Disinfectant;

Hemoclean C Hemodiálisis units Cleaning and Disinfectant;

Scotelin Endoscope and Surgical instruments Cleaning and Steriliant;

Multipose Surgical Instruments Cleaning & Disinfectant. Skin, Minor cuts and Abrasions Disinfection.

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.