



Product Service

CERTIFICATE

No. Q1N 17 11 95885 001

Holder of Certificate: HEMOCLEAN CO., LTD.

 66, Centum jungang-ro, Haeundae-gu
 (U-dong, Centum T-tower) 705-ho
 Busan 48059
 REPUBLIC OF KOREA

Facility(ies):

 HEMOCLEAN CO., LTD.
 66, Centum jungang-ro, Haeundae-gu, (U-dong,
 Centum T-tower) 705-ho, Busan 48059,
 REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate:

 Design, Development and Production
 for sterile single use dialyzer, bloodline,
 AVF needle for Hemodialysis,
 Acidic and Sodium Bicarbonate Concentrate,
 Sodium Bicarbonate Powder Cartridge
 and Bag for Hemodialysis and
 Disinfectants for Hemodialysis Unit

**Applied
Standard(s):**

 EN ISO 13485:2012 + AC:2012
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2003 + Cor. 1:2009)
 DIN EN ISO 13485:2012
 Upgrade required until 2019-03-31

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

74945436

Valid from:

2018-01-26

Valid until:

2021-01-25

Date, 2018-01-26

Stefan Preiß



Page 1 of 1

