

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nephros, Inc.
380 Lackawanna Place
South Orange
New Jersey
07079
USA

Facility ID Number: F003106

Holds Certificate No:

MDSAP 701534

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and development, and manufacture of high permeability hemodialyzers and dialysate water filters for the area of end stage renal disease therapy and point of use water filters for the area of infection control.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-11-25

Effective Date: 2023-06-23

Expiry Date: 2026-06-22



BSI Group America Inc. is an MDSAP recognised auditing organization

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