

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

Holds Certificate Number:

FM 703314

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

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 Global Regulatory & Quality

Original Registration Date: 2010-04-13

Latest Revision Date: 2025-02-17

Effective Date: 2023-06-23

Expiry Date: 2026-06-22

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Certificate No: FM 703314

Location

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

Registered Activities

The design and development, manufacture and distribution 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.

Nephros, Inc.
30 Leslie Court
Whippany
New Jersey
07981
USA

Warehousing, Storage, Materials Handling and Distribution.



Original Registration Date: 2010-04-13

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