



DNV

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000481470-PA-MDSAP-USA

Initial certification date:
2022-08-26

Expiry Date:
2025-08-25

This is to certify that the management system of

Organ Recovery Systems, Inc.

One Pierce Place, Suite 475W, Itasca, IL, 60143, USA

DNV REP– F005879

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

This certificate is valid for the following scope:

The Design, Development, Manufacture, Service and Distribution of Kidney Transporters, Perfusion Circuits, Drapes, Cannulas, Perfusion Solutions and Preservation Solutions for the recovery, treatment, preservation, transport and storage of Kidneys.

Place
Høvik

Effective Date:
2022-08-26



DNV is an MDSAP authorised
auditing organization



For the issuing office:

DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Yury Sumtsov
Certificate Authorizer

Lack of fulfillment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

All our Certificates are in blockchain system and as a first step you can validate the certificate details by scanning the QR code on the Certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacturer name.



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Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Organ Recovery Systems, Inc. (F005879)	One Pierce Place, Suite 475W, Itasca, IL, 60143, USA	The Design, Development, Manufacture, Service and Distribution of Kidney Transporters, Perfusion Circuits, Drapes, Cannulas, Perfusion Solutions and Preservation Solutions for the recovery, treatment, preservation, transport and storage of Kidneys.
Organ Recovery Systems, Inc. (F006094)	3016 Corner Road, Warrior, AL, 35180, USA	The Evaluation and Testing of Kidney Transporters, Perfusion Circuits, Drapes, Cannulas, Perfusion Solutions and Preservation Solutions for the recovery, treatment, preservation, transport and storage of Kidneys.

