



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
10000481470-PA-MDSAP-USA

Initial certification date:  
2022-08-26

Expiry Date:  
2028-08-25

This is to certify that the management system of  
**Organ Recovery Systems, Inc.**

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

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. 665/2022  
- RDC ANVISA n. 551/2021  
- RDC ANVISA n. 67/2009

**Canada:**

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

**United States:**

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

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:  
2025-08-26



DNV is an MDSAP  
Recognized Auditing Organization



For the issuing office:

**DNV Product Assurance AS**  
Veritasveien 1, 1363 Høvik, Norway

**Hazem Tinawi**  
Management Representative

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

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

Your certificate is stored in DNV's secure certificate storage, providing traceability and trust to further enhance the value of your certification. Anyone can easily verify the validity of a certificate and details through the QR code on the certificate or in the link, <https://certificatechecker.dnv.com/>, with the certificate number/manufacturer name.



Certificate no.: 10000481470-PA-MDSAP-USA  
Effective Date: 2025-08-26

## 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.

