EC CERTIFICATE
Full Quality Assurance System

Certificate No.: 10000320758-PA-NA-NOR Project No.: PRJC-509108-2014-MSL-NOR Valid Until: 27 May 2024

This is to certify that the quality system of:

Organ Recovery Systems, Inc.

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

For design, production and final product inspection/testing of:

LIFEPORT KIDNEY TRANSPORTER, INCLUDING ACCESSORIES

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 12 April 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Palani Damodharan
Principal Assessor

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Initial Certification	07 May 2020
1.0	Addition of Kidney Transporter	28 May 2020
2.0	Extension in scope – **LKT200X** new products and editorial corrections **(changes in bold)**	12 April 2021

Products covered by this Certificate:

Product Description	Product Name	Class
LifePort Kidney Transporter GMDN 16461	LKT100P LKT101P	IIa
LifePort Kidney **Transport Disposable** Perfusion Pack GMDN 48039	LKT200	IIa
LifePort Kidney Transporter Disposable Perfusion Pack with Optional Oxygenation Tubing **GMDN 48039**	**LKT200X**	**IIa**
LifePort Kidney Transporter Disposable Cannula GMDN 48039	CAN0720 CAN1035 CAN0003 CAN0005 CAN0008 UCAN0003 UCAN0005 UCAN0007	IIa

	UCAN0009	
LifePort Kidney Transporter Disposable Flexible Couplers GMDN 48039	CAN1000	IIa
LifePort Kidney Transporter Disposable Sterile Drape GMDN 48039	LKT300	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	**Address**
Organ Recovery System, Inc.	One Pierce Place, Suite 475W, Itasca, IL 60143, USA

EU Representative

Emergo Europe, Princessegracht 20, 2514 AP The Hague, The Netherlands

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate