

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 663647**

Issued To:

**Organ Assist Products B.V.
Bornholmstraat 84
9723 AZ Groningen
The Netherlands**

In respect of:

The design and manufacture of Extracorporeal Organ Perfusion Equipment.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-11-25**Date: **2021-04-29**Expiry Date: **2024-05-26****...making excellence a habit.™**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

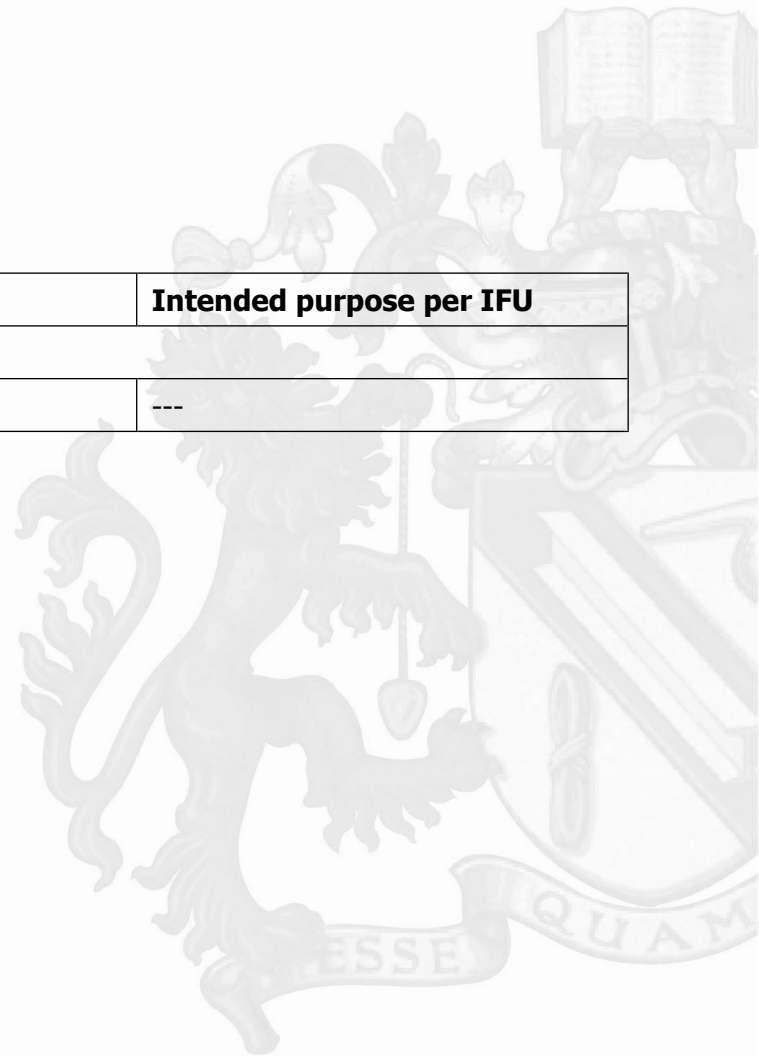
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Supplementary Information to CE 663647

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Device code	Device Name	Intended purpose per IFU
Class IIa		
MD 1101	Organ Perfusion Devices	---



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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 663647**
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Subcontractor:

Service(s) supplied

Variass Medical Systems B.V.
Nipkowlaan 5
9207 JA Drachten
The Netherlands

Manufacture

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Certificate History

Certificate No: **CE 663647**
 Date: **2021-04-29**
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Date	Reference Number	Action
25 November 2016	8634272	First issue. Products previously covered under CE 508111.
06 February 2019	8855761	Traceable to NB 0086.
Current	3421950	Renewal. Addition of device table.

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