By Royal Charter

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**

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Supplementary Information to CE 663647

Issued To:

Organ Assist Products B.V.
Bornholmstraat 84
9723 AZ Groningen
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Device code	Device Name	Intended purpose per IFU
Class IIa		
MD 1101	Organ Perfusion Devices	---

First Issued: **2016-11-25** Date: **2021-04-29** Expiry Date: **2024-05-26**

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

List of Significant Subcontractors

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

Certificate No:	**CE 663647**
Date:	**2021-04-29**
Issued To:	**Organ Assist Products B.V.** **Bornholmstraat 84** **9723 AZ Groningen** **The Netherlands**

Subcontractor:	**Service(s) supplied**
Variass Medical Systems B.V. Nipkowlaan 5 9207 JA Drachten The Netherlands	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 663647**
Date: **2021-04-29**
Issued To: **Organ Assist Products B.V.**
Bornholmstraat 84
9723 AZ Groningen
The Netherlands

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.