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.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 663647

Issued To:

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

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**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

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**

...making excellence a habit.™

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.
29 April 2021	3421950	Renewal. Addition of device table.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
13 October 2021	3554088	Change of legal manufacturer name from: 'Organ Assist Products B.V.' to 'XVIVO B.V.'

...making excellence a habit.™

Inspiring trust for a more resilient world.

13 October 2021

XVIVO B.V.
Bornholmstraat 84
9723 AZ Groningen
The Netherlands

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 663647	93/42/EEC Annex II excluding Section 4	3554088	Change of legal manufacturer name from: 'Organ Assist Products B.V.' to 'XVIVO B.V.'

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl