EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 742864 R000

Manufacturer: XVIVO B.V.

Address:
Bornholmstraat 84
9723 AZ Groningen
The Netherlands

Single Registration Number: NL-MF-000018307

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-03-22** Date: **2022-03-22** Expiry Date: **2027-03-21**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 742864 R000

Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Organ preservation devices	intended to be used for machine perfusion of organs.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Organ preservation sterile perfusion sets	Class IIa
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements. For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

First Issued: **2022-03-22** Date: **2022-03-22** Expiry Date: **2027-03-21**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 742864 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3369789	Issued

First Issued: **2022-03-22** Date: **2022-03-22** Expiry Date: **2027-03-21**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 742864 R000

Date: **2022-03-22**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Applimed SA also trading as CSSR Z.I. Route de Pra de Plan A 9, Châtel-Saint-Denis CH-1618 Switzerland	**ETO Sterilization**
ECM Europe BV Oost-Om 54 Gemert 5422 VZ The Netherlands	**Manufacture**
Unitron Group B.V. Schansestraat 7 4515 RN Ijzendijke The Netherlands	**Manufacture**
Variass Medical Systems B.V. Nipkowlaan 5 9207 JA Drachten The Netherlands	**Manufacture**

...making excellence a habit.™