

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number:

MD 663648

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacturing control, distribution and servicing of organ perfusion or preservation devices and accessories.
The design, development, manufacturing control and distribution of sterile organ perfusion or preservation sets and accessories.
The distribution of accessories for procurement and preservation of donor organs.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-11-15

Latest Revision Date: 2021-11-22

Effective Date: 2021-11-27

Expiry Date: 2024-11-26

Page: 1 of 1



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