state of Minnesota

SECRETARY OF STATE

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country:

United States of America

This Public Document: Certificate

2. has been signed by Choua Thao

3. acting in the capacity of Notary Public, State of Minnesota

4. bears the seal/stamp of Choua Thao, Notary Public, State of Minnesota

CERTIFIED

5. at: St. Paul, Minnesota

6. Date: March 31, 2017

7. by: Secretary of State, State of Minnesota

8. File No: 9436606-3

9. Seal/Stamp:

10. Signature:



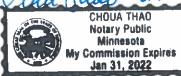
Steve Simon

Secretary of State

CRT2 / 10.13

DAKKS

As a registered Notary Public for the State of Minnesota, I hereby certify that this is a true and accurate copy of the original document. The original is filed at Medtronic Inc.





31- LAR-20

Product Service

CERTIFICATE

No. Q1N 17 02 39709 01074

Holder of Certificate:

Medtronic Inc.

710 Medtronic Parkway N.E. Minneapolis MN 55432

USA

Certification Mark:





Scope of Certificate:

Design, Development, Manufacturing, Distribution and Service of Near-Patient Coagulation Analyzer, Coagulation and QC Cartridges, Autotransfusion System & Associated Disposables, Centrifugal Blood Pumps (coated & uncoated), Bio Console **Drive Units, Flow Monitoring Systems** (coated & uncoated), Bio Cal Blood Temp. Controller, Temp Monitoring Systems & Associated Disposables, Blood Monitoring Systems (e.g. TMCs) (coated & uncoated, Cardioplegia Delivery Systems (coated & uncoated), Disposable Blood Handling Devices used for open heart surgery (e.g. tubing, connectors) (coated & uncoated), Arterial Filters (coated & uncoated), Oxygenerators including heat exchangers, with and without Cardiotomy Venous Reservoirs(coated & uncoated), Cardiotomy Venous Reservoirs (coated & uncoated) Venous Reservoir Bags (coated & uncoated), Disposable Medical Devices for Drainage Systems, Perfusion Related Equipment, Cannulae

(coated & uncoated) and manufacture of Intravascular Catheters, Tissue Positioning/Stabilizing Devices, Surgical Retractors and Related Accessories, Surgical site Clearing Devices, Intravascular Shunts, Devices for Anastomotic and Tissue/Prosthetic Material

Approximation and Removal

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

72117721

Valid from:

2017-04-01

Valid until:

2020-03-31

Date, 2017-03-29

Stefan Preiß

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CERTIFICATE No. Q1N 17 02 39709 01074

Applied Standard(s): EN ISO 13485:2012 + AC:2012

Medical devices - Quality management systems -

Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009) DIN EN ISO 13485:2012

Facility(ies):

Medtronic Perfusion Systems

7611 Northland Drive, Minneapolis, MN 55428, USA

Medtronic Perfusion Systems

18501 East Plaza Drive, Parker CO 80134-9061, USA

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