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Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1263 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis MN 55432
USA

Product Category(ies):

- **Autotransfusion Systems and Associated Disposables**
- **Centrifugal Blood Pumps**
- **Bio-Console Drive Units**
- **Flow Monitoring Systems**
- **Bio-Cal Blood Temperature Controller**
- **Temperature Monitoring Systems and Associated Disposables**
- **Blood Monitoring Systems**
- **Cardioplegia Delivery Systems**
- **Disposable Blood Handling Devices used for Open Heart Surgery**
- **Arterial Filters**
- **Oxygenators including Heat Exchangers, with and without Cardiotomy Reservoirs**
- **Cardiotomy Venous Reservoirs**
- **Venous Reservoir Bags**
- **Perfusion Equipment and Disposable Perfusion Devices**
- **Disposable Medical Devices for Drainage Systems**
- **Disposable Medical Devices for use in Cardiopulmonary Surgery: Cardioplegia, Cannulae, Venting, Suction**
- **Pressure Display System & related accessories of class IIa**
- **Tissue Positioning/Stabilizing Devices**
- **Surgical Site Clearing Devices**
- **Intravascular Shunts**
- **Surgical Retractors**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final

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inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72150396

Valid from: 2020-02-12
Valid until: 2024-05-26

Date, 2020-02-12

Christoph Dicks
Head of Certification/Notified Body

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Facility(ies):

Medtronic Mexico S.de R.L.de CV
Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, MEXICO

Medtronic Perfusion Systems
7611 Northland Drive, Minneapolis, MN 55428, USA

Medtronic, Inc.
710 Medtronic Parkway, Minneapolis MN 55432, USA

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