Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 039709 1280 Rev. 00

Manufacturer	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Product Category(ies):	**Customized Device Packs for use in Cardiopulmonary Surgical Procedures**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72153906

Valid from: 2019-12-12
Valid until: 2024-05-26

Date, 2019-12-12

Digitally signed by Kojevnikov Dmitrii
Date: 2024.09.17 15:55:49 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 039709 1280 Rev. 00

Facility(ies):

Medtronic Cardiac Surgery Division Europe
Valkenhuizerlaan 16, 6466 ND Kerkrade, THE NETHERLANDS

Parameter:

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®