By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 702496**

Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis
Minnesota
55432
USA

In respect of:

Valiant Navion Thoracic Stent Graft System

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Albert Roossien, Regulatory Lead

First Issued: **2018-11-07** Date: **2018-11-07** Expiry Date: **2023-11-06**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
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The catalogue number for the Valiant Navion Thoracic Stent Graft System is constructed in the following manner:

Product name-Proximal Graft Diameter-Distal Graft Diameter-Distal Design-Graft Covered Length-Delivery System, i.e. VNMF2020C96TE

Valiant Navion Thoracic Stent Graft System:

Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
VNMF2020C96TE	Valiant Navion Thoracic Stent Graft System	FreeFlo Straight	The Valiant Navion thoracic stent graft system is indicated for treatment of diseases of the descending thoracic aorta, including, but not limited to, aneurysms, dissections,	Class III Implant
VNMF2222C96TE		FreeFlo Straight		Class III Implant
VNMF2525C96TE		FreeFlo Straight		Class III Implant
VNMF2222C185TE		FreeFlo Straight		Class III Implant
VNMF2525C185TE		FreeFlo Straight		Class III Implant
VNMF3434C59TE		FreeFlo Straight		Class III Implant
VNMF3737C59TE		FreeFlo Straight		Class III Implant

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
VNMF2828C97TE	Valiant Navion Thoracic Stent Graft System	FreeFlo Straight	and blunt traumatic aortic injuries (BTAIs). The Valiant Navion thoracic stent graft is indicated for exclusion of the aneurysm, the false lumen, or site of rupture, and the restoration of blood flow through the stent graft lumen. The device is intended for use in patients who are candidates for conventional surgical repair, and in patients who are not candidates for conventional surgical repair due to pre-existing risk factors.	Class III Implant
VNMF3131C97TE		FreeFlo Straight		Class III Implant
VNMF3434C97TE		FreeFlo Straight		Class III Implant
VNMF3737C97TE		FreeFlo Straight		Class III Implant
VNMF2828C174TE		FreeFlo Straight		Class III Implant
VNMF3131C174TE		FreeFlo Straight		Class III Implant
VNMF3434C174TE		FreeFlo Straight		Class III Implant
VNMF3737C174TE		FreeFlo Straight		Class III Implant
VNMF3131C229TE		FreeFlo Straight		Class III Implant
VNMF3434C229TE		FreeFlo Straight		Class III Implant
VNMF3737C229TE		FreeFlo Straight		Class III Implant
VNMF4040C62TE		FreeFlo Straight		Class III Implant
VNMF4343C62TE		FreeFlo Straight		Class III Implant
VNMF4646C62TE		FreeFlo Straight		Class III Implant
VNMF4040C103TE		FreeFlo Straight		Class III Implant
VNMF4343C103TE		FreeFlo Straight		Class III Implant
VNMF4646C103TE		FreeFlo Straight		Class III Implant
VNMF4040C183TE		FreeFlo Straight		Class III Implant
VNMF4343C183TE		FreeFlo Straight		Class III Implant
VNMF4646C183TE		FreeFlo Straight		Class III Implant
VNMF4040C223TE		FreeFlo Straight		Class III Implant

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
VNMF4343C223TE	Valiant Navion Thoracic Stent Graft System	FreeFlo Straight		Class III Implant
VNMF4646C223TE		FreeFlo Straight		Class III Implant
VNMC2020C94TE		CoveredSeal Straight		Class III Implant
VNMC2222C94TE		CoveredSeal Straight		Class III Implant
VNMC2525C94TE		CoveredSeal Straight		Class III Implant
VNMC2222C180TE		CoveredSeal Straight		Class III Implant
VNMC2525C180TE		CoveredSeal Straight		Class III Implant
VNMC3434C52TE		CoveredSeal Straight		Class III Implant
VNMC3737C52TE		CoveredSeal Straight		Class III Implant
VNMC2828C90TE		CoveredSeal Straight		Class III Implant
VNMC3131C90TE		CoveredSeal Straight		Class III Implant
VNMC3434C90TE		CoveredSeal Straight		Class III Implant
VNMC3737C90TE		CoveredSeal Straight		Class III Implant
VNMC2828C182TE		CoveredSeal Straight		Class III Implant
VNMC3131C182TE		CoveredSeal Straight		Class III Implant
VNMC3434C182TE		CoveredSeal Straight		Class III Implant
VNMC3737C182TE		CoveredSeal Straight		Class III Implant
VNMC3131C223TE		CoveredSeal Straight		Class III Implant
VNMC3434C223TE		CoveredSeal Straight		Class III Implant
VNMC3737C223TE		CoveredSeal Straight		Class III Implant
VNMC4040C55TE		CoveredSeal Straight		Class III Implant

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
VNMC4343C55TE	Valiant Navion Thoracic Stent Graft System	CoveredSeal Straight		Class III Implant
VNMC4646C55TE		CoveredSeal Straight		Class III Implant
VNMC4040C95TE		CoveredSeal Straight		Class III Implant
VNMC4343C95TE		CoveredSeal Straight		Class III Implant
VNMC4646C95TE		CoveredSeal Straight		Class III Implant
VNMC4040C175TE		CoveredSeal Straight		Class III Implant
VNMC4343C175TE		CoveredSeal Straight		Class III Implant
VNMC4646C175TE		CoveredSeal Straight		Class III Implant
VNMC4040C218TE		CoveredSeal Straight		Class III Implant
VNMC4343C218TE		CoveredSeal Straight		Class III Implant
VNMC4646C218TE		CoveredSeal Straight		Class III Implant
VNMF2520C185TE		FreeFlo Tapered		Class III Implant
VNMF2822C173TE		FreeFlo Tapered		Class III Implant
VNMF3125C173TE		FreeFlo Tapered		Class III Implant
VNMF3428C173TE		FreeFlo Tapered		Class III Implant
VNMF3731C173TE		FreeFlo Tapered		Class III Implant
VNMF4034C185TE		FreeFlo Tapered		Class III Implant
VNMF4337C185TE		FreeFlo Tapered		Class III Implant
VNMF4640C185TE		FreeFlo Tapered		Class III Implant
VNMC2520C186TE		CoveredSeal Tapered		Class III Implant
VNMC2822C207TE		CoveredSeal Tapered		Class III Implant
VNMC3125C207TE		CoveredSeal Tapered		Class III Implant

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
VNMC3428C207TE	Valiant Navion Thoracic Stent Graft System	CoveredSeal Tapered		Class III Implant
VNMC3731C207TE		CoveredSeal Tapered		Class III Implant
VNMC4034C200TE		CoveredSeal Tapered		Class III Implant
VNMC4337C200TE		CoveredSeal Tapered		Class III Implant
VNMC4640C200TE		CoveredSeal Tapered		Class III Implant

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Date	Reference Number	Action
Current	8938948	First Issue.

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