

Certificate

Design Examination

No. CE 525652



Issued to:

Medtronic Inc
710 Medtronic Parkway NE
Minneapolis
Minnesota
55432
USA

In respect of:

Sprinter Legend RX Balloon Dilatation Catheter

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 4.

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

A handwritten signature in black ink, appearing to be 'G. Fenton', written over a horizontal line.

Gary Fenton, Global Assurance Director

First Issued: 17 Oct 2007

Date: 26 Sep 2012

Expiration Date: 16 Oct 2017

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

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Supplementary Information to CE 525652

Issued to:
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USA

Products: Sprinter Legend RX Balloon Dilatation Catheter

Model Name	Model No.
Sprinter Legend RX	SPL12506X
Sprinter Legend RX	SPL12510X
Sprinter Legend RX	SPL12512X
Sprinter Legend RX	SPL12515X
Sprinter Legend RX	SPL12520X
Sprinter Legend RX	SPL15006X
Sprinter Legend RX	SPL15010X
Sprinter Legend RX	SPL15012X
Sprinter Legend RX	SPL15015X
Sprinter Legend RX	SPL15020X
Sprinter Legend RX	SPL20006X
Sprinter Legend RX	SPL20010X
Sprinter Legend RX	SPL20012X
Sprinter Legend RX	SPL20015X
Sprinter Legend RX	SPL20020X
Sprinter Legend RX	SPL20025X

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Model Name	Model No.
Sprinter Legend RX	SPL20030X
Sprinter Legend RX	SPL22506X
Sprinter Legend RX	SPL22510X
Sprinter Legend RX	SPL22512X
Sprinter Legend RX	SPL22515X
Sprinter Legend RX	SPL22520X
Sprinter Legend RX	SPL22525X
Sprinter Legend RX	SPL25006X
Sprinter Legend RX	SPL25010X
Sprinter Legend RX	SPL25012X
Sprinter Legend RX	SPL25015X
Sprinter Legend RX	SPL25020X
Sprinter Legend RX	SPL25025X
Sprinter Legend RX	SPL25030X
Sprinter Legend RX	SPL27506X
Sprinter Legend RX	SPL27512X

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Model Name	Model No.
Sprinter Legend RX	SPL27515X
Sprinter Legend RX	SPL27520X
Sprinter Legend RX	SPL27525X
Sprinter Legend RX	SPL30006X
Sprinter Legend RX	SPL30010X
Sprinter Legend RX	SPL30012X
Sprinter Legend RX	SPL30015X
Sprinter Legend RX	SPL30020X
Sprinter Legend RX	SPL30025X
Sprinter Legend RX	SPL30030X
Sprinter Legend RX	SPL32512X
Sprinter Legend RX	SPL32515X
Sprinter Legend RX	SPL32520X
Sprinter Legend RX	SPL35006X
Sprinter Legend RX	SPL35010X
Sprinter Legend RX	SPL35012X

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Model Name	Model No.
Sprinter Legend RX	SPL35015X
Sprinter Legend RX	SPL35020X
Sprinter Legend RX	SPL35025X
Sprinter Legend RX	SPL35030X
Sprinter Legend RX	SPL37512X
Sprinter Legend RX	SPL37515X
Sprinter Legend RX	SPL37520X
Sprinter Legend RX	SPL40006X
Sprinter Legend RX	SPL40010X
Sprinter Legend RX	SPL40012X
Sprinter Legend RX	SPL40015X
Sprinter Legend RX	SPL40020X
Sprinter Legend RX	SPL40025X
Sprinter Legend RX	SPL40030X

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History of Certificate

Date	Reference Number	Action
17 October 2007	10091718	First issue
27 September 2010	10116887	Approval of Cambus Medical as an alternative supplier of the Hypotube component
26 September 2012	10135817	Certificate renewal

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