

EC Design-Examination Certificate

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

No.**CE 01439****Issued To:**

**Cordis Corporation
14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA**

In respect of:

Cordis Steerable Guidewires, Cordis Diagnostic Guidewires and Cordis Short Transition Steerable Guidewires.

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1996-11-08**

Date: **2020-02-05**

Expiry Date: **2024-05-26**

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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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EC Design-Examination Certificate

Supplementary Information to CE 01439

Issued To:

Cordis Corporation
14201 North West 60th Avenue
Miami Lakes
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USA

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
595-014	Cordis ATW Steerable Guidewires	ATW	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
595-J014	Cordis ATW Steerable Guidewires	ATW	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
595-X014	Cordis ATW Steerable Guidewires	ATW	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
595-Y014	Cordis ATW Steerable Guidewires	ATW	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
595-E014	Cordis ATW Steerable Guidewires	ATW	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
595-EJ014	Cordis ATW Steerable Guidewires	ATW	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
595-EX014	Cordis ATW Steerable Guidewires	ATW	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
595-EY014	Cordis ATW Steerable Guidewires	ATW	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
595-M014	Cordis ATW Marker Wire Steerable Guidewires	ATW Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6

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595-MJ014	Cordis ATW Marker Wire Steerable Guidewires	ATW Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6
595-MX014	Cordis ATW Marker Wire Steerable Guidewires	ATW Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6
595-MY014	Cordis ATW Marker Wire Steerable Guidewires	ATW Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6

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595-ME014	Cordis ATW Marker Wire Steerable Guidewires	ATW Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6
595-MEJ014	Cordis ATW Marker Wire Steerable Guidewires	ATW Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6
595-MEX014	Cordis ATW Marker Wire Steerable Guidewires	ATW Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6

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595-MEY014	Cordis ATW Marker Wire Steerable Guidewires	ATW Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6
518-014	Cordis ATW Marker Intermediate Guidewire	ATW Marker Intermediate	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6
518-E14	Cordis ATW Marker Intermediate Guidewire	ATW Marker Intermediate	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6

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518-J014	Cordis ATW Marker Intermediate Guidewire	ATW Marker Intermediate	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6
518-EJ14	Cordis ATW Marker Intermediate Guidewire	ATW Marker Intermediate	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6
518-X014	Cordis ATW Marker Intermediate Guidewire	ATW Marker Intermediate	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6

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518-EX14	Cordis ATW Marker Intermediate Guidewire	ATW Marker Intermediate	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6
518-Y014	Cordis ATW Marker Intermediate Guidewire	ATW Marker Intermediate	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6
518-EY14	Cordis ATW Marker Intermediate Guidewire	ATW Marker Intermediate	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
502-524	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-536	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-522	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-521	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-521F	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-521E	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-526	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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502-519	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-531	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-534	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-587	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-585	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-585F	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-585E	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
502-589	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-535	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-535F	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-535E	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-576	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-533	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-520	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
502-520F	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-584E	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-584	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-584F	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-588	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-525	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-525E	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
502-575	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-530	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-716	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-717	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-537	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-538	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-570	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
502-539	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-540	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-550	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-532	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-582A	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-701	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-572A	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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502-568A	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-571A	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-574A	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-570A	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-573A	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-456	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-452	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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502-453	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-453F	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-453E	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-454	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
502-572	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-571	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-569	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-542	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-560	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-541	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-563	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
502-544	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-545	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-561	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-580	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-581	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-703	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-704	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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502-581A	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-442E	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-554	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-558	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-555	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-557	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-553	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
502-731	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-733	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-735	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-726	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-728	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-542E	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-546	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
502-548	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-549	Cordis Emerald Diagnostic Guidewires	Emerald	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	Class III Rule 6
502-012C	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
502-014C	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
502-014B	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
502-014X	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
502-014AJ	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
502-014A	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
502-012CJ	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
502-012CX	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
502-014CJ	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6

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502-014CX	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
502-014CY	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
502-014BJ	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
502-014BY	Cordis Reflex Guidewires	Reflex	Cordis Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the vasculature.	Class III Rule 6
547-114	Cordis Shinobi Steerable Guidewires	Shinobi	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
547-114X	Cordis Shinobi Steerable Guidewires	Shinobi	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
547-214	Cordis Shinobi Plus Steerable Guidewires	Shinobi Plus	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
547-214X	Cordis Shinobi Plus Steerable Guidewires	Shinobi Plus	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
507-914	Cordis Stabilizer Steerable Guidewires	Stabilizer	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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507-914J	Cordis Stabilizer Steerable Guidewires	Stabilizer	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
507-914X	Cordis Stabilizer Steerable Guidewires	Stabilizer	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
507-914Y	Cordis Stabilizer Steerable Guidewires	Stabilizer	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
507-714	Cordis Stabilizer Steerable Guidewires	Stabilizer	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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507-714J	Cordis Stabilizer Steerable Guidewires	Stabilizer	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
507-714X	Cordis Stabilizer Steerable Guidewires	Stabilizer	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
507-714Y	Cordis Stabilizer Steerable Guidewires	Stabilizer	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
507-114	Cordis Stabilizer Plus Steerable Guidewires	Stabilizer Plus	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
507-114J	Cordis Stabilizer Plus Steerable Guidewires	Stabilizer Plus	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
507-114X	Cordis Stabilizer Plus Steerable Guidewires	Stabilizer Plus	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
507-114Y	Cordis Stabilizer Plus Steerable Guidewires	Stabilizer Plus	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
527-914	Cordis Stabilizer XS	Stabilizer XS	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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527-914J	Cordis Stabilizer XS	Stabilizer XS	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
527-914X	Cordis Stabilizer XS	Stabilizer XS	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
527-914Y	Cordis Stabilizer XS	Stabilizer XS	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
507-180S	Cordis Stabilizer Support Steerable Guidewires	Stabilizer Support	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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507-300S	Cordis Stabilizer Support Steerable Guidewires	Stabilizer Support	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
527-180E	Cordis Stabilizer Extra Support Steerable Guidewires	Stabilizer Extra Support	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
527-300E	Cordis Stabilizer Extra Support Steerable Guidewires	Stabilizer Extra Support	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
518-224	Cordis Stabilizer Marker Wire Steerable Guidewires	Stabilizer Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
518-224J	Cordis Stabilizer Marker Wire Steerable Guidewires	Stabilizer Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
518-224X	Cordis Stabilizer Marker Wire Steerable Guidewires	Stabilizer Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
518-224Y	Cordis Stabilizer Marker Wire Steerable Guidewires	Stabilizer Marker Wire	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
512-143	Cordis Wizdom Steerable Guidewires	Wizdom	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
512-143J	Cordis Wizdom Steerable Guidewires	Wizdom	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
512-143X	Cordis Wizdom Steerable Guidewires	Wizdom	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
512-143Y	Cordis Wizdom Steerable Guidewires	Wizdom	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
512-142	Cordis Wizdom Steerable Guidewires	Wizdom	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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512-142J	Cordis Wizdom Steerable Guidewires	Wizdom	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
512-142X	Cordis Wizdom Steerable Guidewires	Wizdom	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
512-142Y	Cordis Wizdom Steerable Guidewires	Wizdom	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
537-114	Cordis Wizdom Short Transition Steerable Guidewires	Wizdom ST	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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537-114J	Cordis Wizdom Short Transition Steerable Guidewires	Wizdom ST	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
537-114X	Cordis Wizdom Short Transition Steerable Guidewires	Wizdom ST	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6
537-114Y	Cordis Wizdom Short Transition Steerable Guidewires	Wizdom ST	Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.	Class III Rule 6

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Certificate History

Date	Reference Number	Action
08 November 1996	MD 000184	First Issue
14 January 1997	MD 000191	Cordis Short Transition Steerable guidewires added to scope
02 December 1997	MD 000285	Line extension to Steerable guidewires
01 May 1998	MD 000396	Line extension to Diagnostic guidewires, Steerable guidewires and Short Transition Steerable guidewires
16 August 1999	MD 000600	Addition of Cordis all track wire (ATW) Steerable guidewires to the product listing
12 April 2000	10011848	Addition of Cordis all track wire (ATW) marker wire Steerable guidewires to the product listing
08 November 2001	10031856	5 Year renewal
11 November 2003	10052519	Method of manufacture change to the ATW/ATW marker wire
17 February 2004	10055066 and 10055349	Amendment to include outsourcing of manufacture to Lake Region Medical Inc and Medsource Technologies and PTFE coating method change.
01 June 2004	10056269	Addition of ATW Marker Wire Intermediate catalogue numbers
01 December 2006	10082158	Certificate renewal

First Issued: **1996-11-08**

Date: **2020-02-05**

Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 01439

Issued To:

Cordis Corporation
14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA

Certificate History

Date	Reference Number	Action
30 August 2007	10091020	Addition of the following catalogue numbers 507-180S, 507-300S, 527-180E, 527-300E
23 March 2009	10102626	Addition of Isotron Ireland Limited, Tullamore, Offaly, Ireland as an alternative sterilization site which is controlled by Lake Region Medical Limited, Ireland for Emerald Diagnostic Guidewires, Diagnostic Guidewire Modified Standards (SMxxxx, SMxxxxx, SLxxxx), Shinobi Steerable Guidewires, Steerable Guidewire Modified Standards (SMxxxx, SMxxxxx, SLxxxx) and 'All Track Wires (ATW)'.
12 October 2010	10117785	Addition of Steris Isomedix Service Minneapolis, MN as alternative sterilization site, which is controlled by subcontractor Lake Region Medical, Chaska, MN.
03 March 2011	7645209	Update the wildcard scheme used to describe the Shinobi and Shinobi Plus Straight and "J" Tip products to align with the product codes in the original review MD000285
08 November 2011	10130988	Certificate renewal

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Certificate History

Date	Reference Number	Action
24 April 2015	10154300	Add Lake Region Medical in New Ross, Ireland as a manufacturing site and add Synergy Health Tullamore, Ireland contracted by Lake Region Medical as an alternate sterilization site for the Stabilizer and Wizdom product families.
04 February 2016	10160465	Change affecting DuPont Tyvek 1073B packaging material – all product codes are affected.
03 November 2016	10166344	Certificate Renewal.
04 February 2019	9653297	Addition of alternate sterilization site, Synergy Health, Thorne, UK contracted by Lake Region Medical for Steerable Guidewires, Diagnostic Guidewires and Short Transition Guidewires..
06 March 2019	7780552	Traceable to NB 0086.
Current	9703943	Certificate renewal. Marvel guidewires 502-xxx and 502-xxx(X) removed from the certificate scope. Modified standards SMXXXX, SMXXXXX and SLXXXX removed from the certificate scope. Administrative change on product table.

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