

100568032 Attachment 1 – Declaration of Conformity (MDD and MDR), Rev 2

Only Native File to be used

DoC Number/Revision: 10645976 Rev 21

DECLARATION OF CONFORMITY

We, Cordis Corporation, declare that the products covered in this Declaration of Conformity meet the provision of the Council Directive 93/42/EEC for Medical Devices as amended by 2007/47/EC and as transposed in the national laws of the Member States.

Technical Documentation Number	2021-03-30
Manufacturer's Name	Cordis Corporation
Manufacturer's Address	14201 North West 60th Avenue, Miami Lakes, FL 33014
Manufactured under Contract by:	Lake Region Medical Ltd. Butlersland New Ross Co. Wexford Ireland The following guidewires are manufactured in the above site: Cordis Emerald Diagnostic Guidewires, Cordis Stabilizer Balanced Performance Steerable Guidewires, Cordis Stabilizer Plus Steerable Guidewires, Cordis Stabilizer XS Steerable Guidewires, Cordis Stabilizer Support Steerable Guidewires, Cordis Stabilizer Extra Support Steerable Guidewires, Cordis Stabilizer Marker Wire Steerable Guidewires, Cordis Shinobi Steerable Guidewires, Cordis Shinobi Plus Steerable Guidewires, Cordis Wizdom Steerable Guidewires, Cordis ATW Steerable Guidewires, Cordis ATW Marker Wire Steerable Guidewires, Cordis ATW Marker Wire Intermediate Steerable Guidewires and Cordis Wizdom ST- Short Transition Steerable Guidewires. Lake Region Medical 340 Lake Hazeltine Drive Chaska, MN 55318 USA The Cordis Reflex Steerable Guidewires are manufactured at the above site.
Authorized Representative's Name and Address	Cordis Cashel, Cahir Road, Cashel, Co. Tipperary, Ireland
Notified body's Name and Identification Number	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam

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DECLARATION OF CONFORMITY	
	Identification Number: 2797
CE Certificate Number	CE 01439
Product Name	Cordis Steerable Guidewires, Cordis Diagnostic Guidewires and Cordis Short Transition Steerable Guidewires.
Basic UDI-DI	Not Applicable.
Product Code(s) and Description	Refer to Attachment 1.
Classification and Rule	Class III (Annex IX, Rule 6)
Single Registration Number	Not Applicable.
Common Specifications	Not Applicable.
Conformity assessment	In order to affix CE marking, Cordis Corporation has followed the procedure relating to the EC Declaration of Conformity set out in Annex II, Clause 4 of the Directive 93/42/EEC as last amended.
GMDN Code	35094

SIGNATURE SECTION			
This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.			
Place of Issue	14201 North West 60th Avenue, Miami Lakes, FL 33014		
Signature	Linda Ruedy  <i>Electronically signed by: Linda Ruedy Reason: Approved Date: Mar 31, 2021 13:23 PDT</i>	Date	Mar 31, 2021
Title/Position	Director, Global Regulatory Affairs		
Signature	Matt Hedrick  <i>Electronically signed by: Matt Hedrick Reason: Approved Date: Mar 30, 2021 18:16 EDT</i>	Date	Mar 30, 2021
Title/Position	Director, Global QRA		

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ATTACHMENT 1

Product Code List				
Product Code	Product Description	Basic UDI-DI	GMDN Code	Classification and Rule
518-014	ATW Marker Wire Intermediate, 195CM, Straight, 1-Pack	N/A	35094	Class III (Rule 6)
518-E14	ATW Marker Wire Intermediate, 195CM, Straight, 5-Pack	N/A	35094	Class III (Rule 6)
518-EJ14	ATW Marker Wire Intermediate, 195CM, J, 5-Pack	N/A	35094	Class III (Rule 6)
518-EX14	ATW Marker Wire Intermediate, 300CM, Straight, 5-Pack	N/A	35094	Class III (Rule 6)
518-EY14	ATW Marker Wire Intermediate, 300CM, J, 5-Pack	N/A	35094	Class III (Rule 6)
518-J014	ATW Marker Wire Intermediate, 195CM, J, 1-Pack	N/A	35094	Class III (Rule 6)
518-X014	ATW Marker Wire Intermediate, 300CM, Straight, 1-Pack	N/A	35094	Class III (Rule 6)
518-Y014	ATW Marker Wire Intermediate, 300CM, J, 1-Pack	N/A	35094	Class III (Rule 6)
595-014	SGW ATW .014 STR FLOPPY 195CM	N/A	35094	Class III (Rule 6)
595-E014	SGW ATW .014 STR FLOPPY 195CM	N/A	35094	Class III (Rule 6)
595-EJ014	SGW ATW .014 J FLOPPY 195CM	N/A	35094	Class III (Rule 6)
595-EX014	SGW ATW .014 STR FLOPPY 300CM	N/A	35094	Class III (Rule 6)
595-EY014	SGW ATW .014 J FLOPPY 300CM	N/A	35094	Class III (Rule 6)
595-J014	SGW ATW .014 J FLOPPY 195CM	N/A	35094	Class III (Rule 6)
595-X014	SGW ATW .014 STR FLOPPY 300CM	N/A	35094	Class III (Rule 6)
595-Y014	SGW ATW .014 J FLOPPY 300CM	N/A	35094	Class III (Rule 6)
595-M014	SGW ATW .014 STR FLOPPY 195CM	N/A	35094	Class III (Rule 6)

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Product Code	Product Description	Basic UDI-DI	GMDN Code	Classification and Rule
595-ME014	SGW ATW .014 STR FLOPPY 195CM	N/A	35094	Class III (Rule 6)
595-MEJ014	SGW ATW .014 J FLOPPY 195CM	N/A	35094	Class III (Rule 6)
595-MEX014	SGW ATW .014 STR FLOPPY 300CM	N/A	35094	Class III (Rule 6)
595-MEY014	SGW ATW .014 J FLOPPY 300CM	N/A	35094	Class III (Rule 6)
595-MJ014	SGW ATW .014 J FLOPPY 195CM	N/A	35094	Class III (Rule 6)
595-MX014	SGW ATW.014 STR FLOPPY 300CM	N/A	35094	Class III (Rule 6)
595-MY014	SGW ATW .014 J FLOPPY 300CM	N/A	35094	Class III (Rule 6)
502-442E	DGW .035 MC STR 260CM AMP SS	N/A	35094	Class III (Rule 6)
502-452	DGW .025 FC J3MM 260CM TEF	N/A	35094	Class III (Rule 6)
502-453	DGW .038 FC J3MM 260CM TEF	N/A	35094	Class III (Rule 6)
502-453E	DGW .038 FC J3MM 260CM TEF FIR	N/A	35094	Class III (Rule 6)
502-453F	DGW .038 FC J3MM 260CM TEF EXT	N/A	35094	Class III (Rule 6)
502-454	DGW .032 FC J3MM 260CM TEF	N/A	35094	Class III (Rule 6)
502-455	DGW .035 FC J3MM 260CM TEF	N/A	35094	Class III (Rule 6)
502-455E	DGW .035 FC J3MM 260CM TEF FRM	N/A	35094	Class III (Rule 6)
502-455F	DGW .035 FC J3MM 260CM TEF EXT	N/A	35094	Class III (Rule 6)
502-456	DGW .018 FC J3MM 260CM TEF	N/A	35094	Class III (Rule 6)
502-519	EMERALD GUIDEWIRES (OEM)	N/A	35094	Class III (Rule 6)
502-520	DGW .038 FC J3MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-520F	DGW .038 FC J3MM 150CM FIRM	N/A	35094	Class III (Rule 6)

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Product Code	Product Description	Basic UDI-DI	GMDN Code	Classification and Rule
502-521	DGW .035 FC J3MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-521E	DGW .035 FC J3MM 150CM TEF EXT	N/A	35094	Class III (Rule 6)
502-521F	DGW .035 FC J3MM 150CM TEF HEP	N/A	35094	Class III (Rule 6)
502-522	DGW .030 FC J3MM 150CM TEF HD	N/A	35094	Class III (Rule 6)
502-524	DGW .025 FC J3MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-525	DGW .038 FC J15MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-525E	DGW .038 FC J15MM 150CM TEF EX	N/A	35094	Class III (Rule 6)
502-526	DGW .032 FC J3MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-530	DGW .065 FC J6MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-531	EMERALD GUIDEWIRES (OEM)	N/A	35094	Class III (Rule 6)
502-532	EMERALD GUIDEWIRES (OEM)	N/A	35094	Class III (Rule 6)
502-533	DGW .038 FC J1.5MM 175CM T HD	N/A	35094	Class III (Rule 6)
502-534	DGW .035 FC J1.5MM 175CM T HD	N/A	35094	Class III (Rule 6)
502-535	DGW .035 FC J15MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-535E	DGW .035 FC J15MM 150CM TEF EX	N/A	35094	Class III (Rule 6)
502-535F	DGW .035 FC J15MM 150CM TEF FI	N/A	35094	Class III (Rule 6)
502-536	DGW .025 FC J15MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-537	DGW .038 FC STR 125CM TEF	N/A	35094	Class III (Rule 6)
502-538	DGW .032 FC STR 125CM TEF	N/A	35094	Class III (Rule 6)
502-539	DGW .025 FC STR 125CM TEF	N/A	35094	Class III (Rule 6)
502-540	DGW .065 FC STR 150CM TEF	N/A	35094	Class III (Rule 6)
502-541	DGW .038 FC STR 150CM TEF	N/A	35094	Class III (Rule 6)

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Product Code	Product Description	Basic UDI-DI	GMDN Code	Classification and Rule
502-542	DGW .035 FC STR 150CM TEF	N/A	35094	Class III (Rule 6)
502-542E	DGW .035 FC 150CM TEF EXT FIRM	N/A	35094	Class III (Rule 6)
502-544	DGW .035 FC STR 150CM TEF LT	N/A	35094	Class III (Rule 6)
502-545	DGW .038 FC STR 150CM TEF LLT	N/A	35094	Class III (Rule 6)
502-546	DGW .035 FC STR 150CM TEF LLT	N/A	35094	Class III (Rule 6)
502-548	DGW .032 FC STR 150CM TEF	N/A	35094	Class III (Rule 6)
502-549	DGW .025 FC STR 150CM TEF	N/A	35094	Class III (Rule 6)
502-550	DGW .038 FC J3MM 150CM SSTEEL	N/A	35094	Class III (Rule 6)
502-553	DGW .038 FC STR 260CM TEF	N/A	35094	Class III (Rule 6)
502-554	DGW .032 FC STR 260CM TEF	N/A	35094	Class III (Rule 6)
502-555	DGW .035 FC STR 260CM TEF	N/A	35094	Class III (Rule 6)
502-557	DGW .038 FC STR 220CM TEF	N/A	35094	Class III (Rule 6)
502-558	DGW .035 FC STR 220CM TEF	N/A	35094	Class III (Rule 6)
502-560	DGW .035 FC STR 150CM TEF LLT	N/A	35094	Class III (Rule 6)
502-561	DGW .038 FC STR 150CM TEF LLT	N/A	35094	Class III (Rule 6)
502-563	E SJ2/FC/ST/150/.035/T	N/A	35094	Class III (Rule 6)
502-568A	DGW .035 MC J3MM 125CM TEF AMP	N/A	35094	Class III (Rule 6)
502-569	DGW .032 MC J3MM 125CM TEF	N/A	35094	Class III (Rule 6)
502-570	DGW .038 MC J3MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-570A	SGW .038 MC J3MM 150CM TEF AMP	N/A	35094	Class III (Rule 6)
502-571	DGW .035 MC J3MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-571A	DGW .035 MC J3MM 150CM TEF AMP	N/A	35094	Class III (Rule 6)

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Product Code	Product Description	Basic UDI-DI	GMDN Code	Classification and Rule
502-572	DGW .032 MC J3MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-572A	DGW .032 MC J3MM 150CM TEF AMP	N/A	35094	Class III (Rule 6)
502-573A	DGW .038 MC J15MM 150CM TEF AM	N/A	35094	Class III (Rule 6)
502-574A	DGW .035 MC J15MM 150CM TEF AM	N/A	35094	Class III (Rule 6)
502-575	DGW .038 MC J15MM 150CM TEF LT	N/A	35094	Class III (Rule 6)
502-576	DGW .035 MC J15MM 150CM TEF LT	N/A	35094	Class III (Rule 6)
502-580	DGW .038 MC STR 150CM TEF	N/A	35094	Class III (Rule 6)
502-581	DGW .035 MC STR 150CM TEF	N/A	35094	Class III (Rule 6)
502-581A	DGW .035 MC STR 150CM TEF AMP	N/A	35094	Class III (Rule 6)
502-582A	DGW .032 MC STR 150CM TEF AMP	N/A	35094	Class III (Rule 6)
502-584	DGW .038 FC J3MM 175CM TEF	N/A	35094	Class III (Rule 6)
502-584E	DGW .038 FC J3MM 175CM TEF EXT	N/A	35094	Class III (Rule 6)
502-584F	DGW .038 FC J3MM 175CM TEF FRM	N/A	35094	Class III (Rule 6)
502-585	DGW .035 FC J3MM 175CM TEF	N/A	35094	Class III (Rule 6)
502-585E	DGW .035 FC J3MM 175CM TEF EXT	N/A	35094	Class III (Rule 6)
502-585F	DGW .035 FC J3MM 175CM TEF FRM	N/A	35094	Class III (Rule 6)
502-587	DGW .035 FC J3MM 150CM TEF LT	N/A	35094	Class III (Rule 6)
502-588	DGW .038 FC J6MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-589	DGW .035 FC J6MM 150CM TEF	N/A	35094	Class III (Rule 6)
502-701	EMERALD GUIDEWIRES (OEM)	N/A	35094	Class III (Rule 6)
502-703	EMERALD GUIDEWIRES (OEM)	N/A	35094	Class III (Rule 6)
502-704	EMERALD GUIDEWIRES (OEM)	N/A	35094	Class III (Rule 6)

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Product Code	Product Description	Basic UDI-DI	GMDN Code	Classification and Rule
502-716	DGW.035 FC R1.5MM 150CM PTFE	N/A	35094	Class III (Rule 6)
502-717	DGW.035 FC R1.5MM 180CM PTFE	N/A	35094	Class III (Rule 6)
502-726	DGW.035 FC STR SS 150CM PTFE	N/A	35094	Class III (Rule 6)
502-728	DGW.035 FC STR SS 180CM PTFE	N/A	35094	Class III (Rule 6)
502-731	DGW.035 FC J3MM SS 150CM PTFE	N/A	35094	Class III (Rule 6)
502-733	DGW.035 FC J3MM SS 180CM PTFE	N/A	35094	Class III (Rule 6)
502-735	DGW.035 FC J3MM SS 260CM PTFE	N/A	35094	Class III (Rule 6)
547-114	SGW SHINOBI 180CM	N/A	35094	Class III (Rule 6)
547-114X	SGW SHINOBI 300CM	N/A	35094	Class III (Rule 6)
547-214	SGW SHINOBI PLUS 180CM	N/A	35094	Class III (Rule 6)
547-214X	SGW SHINOBI PLUS 300 CM	N/A	35094	Class III (Rule 6)
507-114	SGW STAB PLUS .014 180CM ST SS	N/A	35094	Class III (Rule 6)
507-114J	SGW STAB PLUS .014 180CM J SS	N/A	35094	Class III (Rule 6)
507-114X	SGW STAB PLUS .014 300CM ST SS	N/A	35094	Class III (Rule 6)
507-114Y	SGW STAB PLUS .014 300CM J SS	N/A	35094	Class III (Rule 6)
507-180S	SGW .014 STABILIZER 180cm Support	N/A	35094	Class III (Rule 6)
507-300S	SGW .014 STABILIZER 300cm Support	N/A	35094	Class III (Rule 6)
507-714	SGW STABLIZR .014 180CM ST SOF	N/A	35094	Class III (Rule 6)
507-714J	SGW STABLIZR .014 180CM J SOFT	N/A	35094	Class III (Rule 6)
507-714X	SGW STABLIZR .014 300CM ST SOF	N/A	35094	Class III (Rule 6)
507-714Y	SGW STABLIZR .014 300CM J SOFT	N/A	35094	Class III (Rule 6)
507-914	SGW STABLIZR .014 180CM ST SS	N/A	35094	Class III (Rule 6)

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507-914J	SGW STABLIZR .014 180CM J SS	N/A	35094	Class III (Rule 6)
507-914X	SGW STABLIZR .014 300CM ST SS	N/A	35094	Class III (Rule 6)
507-914Y	SGW STABLIZR .014 300CM J SS	N/A	35094	Class III (Rule 6)
518-224	SGW STAB MARKER .014 180 ST SS	N/A	35094	Class III (Rule 6)
518-224J	SGW STAB MARKER .014 180 J SS	N/A	35094	Class III (Rule 6)
518-224X	SGW STAB MARKER .014 300 ST SS	N/A	35094	Class III (Rule 6)
518-224Y	SGW STAB MARKER .014 300 J SS	N/A	35094	Class III (Rule 6)
527-180E	SGW .014 STABILIZER 180cm Extra Support	N/A	35094	Class III (Rule 6)
527-300E	SGW .014 STABILIZER 300cm Extra Support	N/A	35094	Class III (Rule 6)
527-914	SGW STAB XS .014 180CM ST SS	N/A	35094	Class III (Rule 6)
527-914J	SGW STAB XS .014 180CM J SS	N/A	35094	Class III (Rule 6)
527-914X	SGW STAB XS .014 300CM ST SS	N/A	35094	Class III (Rule 6)
527-914Y	SGW STAB XS .014 300CM J SS	N/A	35094	Class III (Rule 6)
502-012C	SGW REFLEX .012/.014 175CM SS	N/A	35094	Class III (Rule 6)
502-012CJ	SGW REFLEX .012/.014 175CMJ SS	N/A	35094	Class III (Rule 6)
502-012CX	SGW REFLEX .012/.014 300CM SS	N/A	35094	Class III (Rule 6)
502-014A	SGW REFLEX .014 175CM STD	N/A	35094	Class III (Rule 6)
502-014AJ	SGW REFLEX .014 175CM J STD	N/A	35094	Class III (Rule 6)
502-014B	SGW REFLEX .014 175CM SOFT	N/A	35094	Class III (Rule 6)
502-014BJ	SGW REFLEX .014 175CM J SOFT	N/A	35094	Class III (Rule 6)
502-014BY	SGW REFLEX .014 300CM SFT J	N/A	35094	Class III (Rule 6)
502-014C	SGW REFLEX .014 175CM SSOFT	N/A	35094	Class III (Rule 6)

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502-014CJ	SGW REFLEX .014 175CM J SSFT	N/A	35094	Class III (Rule 6)
502-014CX	SGW REFLEX .014 300CM SSFT	N/A	35094	Class III (Rule 6)
502-014CY	SGW REFLEX .014 300CM SSFT J	N/A	35094	Class III (Rule 6)
502-014X	SGW REFLEX .014 300CM SOFT	N/A	35094	Class III (Rule 6)
512-142	SGW .014 WIZDOM SOFT 180 ST	N/A	35094	Class III (Rule 6)
512-142J	SGW .014 WIZDOM SOFT 180 J	N/A	35094	Class III (Rule 6)
512-142X	SGW .014 WIZDOM SOFT 300 ST	N/A	35094	Class III (Rule 6)
512-142Y	SGW .014 WIZDOM SOFT 300 J	N/A	35094	Class III (Rule 6)
512-143	SGW .014 WIZDOM SS 180 ST	N/A	35094	Class III (Rule 6)
512-143J	SGW .014 WIZDOM SS 180 J	N/A	35094	Class III (Rule 6)
512-143X	SGW .014 WIZDOM SS 300 ST	N/A	35094	Class III (Rule 6)
512-143Y	SGW .014 WIZDOM SS 300 J	N/A	35094	Class III (Rule 6)
537-114	SGW .014 WIZ ST FLOPPY 180 ST	N/A	35094	Class III (Rule 6)
537-114J	SGW .014 WIZ ST FLOPPY 180 J	N/A	35094	Class III (Rule 6)
537-114X	SGW .014 WIZ ST FLOPPY 300 ST	N/A	35094	Class III (Rule 6)
537-114Y	SGW .014 WIZ ST FLOPPY 300 J	N/A	35094	Class III (Rule 6)

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Final Audit Report

2021-03-31

Created:	2021-03-29
By:	Dunia L Bram (dunia.bram@cardinalhealth.com)
Status:	Signed
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