

EC Design-Examination Certificate

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

No. **CE 560101**
Issued To: **Merit Medical Systems, Inc.**
1600 West Merit Parkway
South Jordan
Utah
84095
USA

In respect of:

InQwire® Diagnostic Guide Wires

InQwire® Amplatz Guide Wires

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: **2010-03-30**

Date: **2020-11-11**

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

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Information and Contact: BSI, Bay 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 33364284.

A member of BSI Group of Companies.

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Supplementary Information to CE 560101

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Intended Purpose per IFU: Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.

Classification: III

#	Catalogue Number	Device Name	Model, Type
1	IQ35F100J15	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).100 cm (39.4").15 mm J-Tip.Standard.....Fixed Core.PTFE Coated.....Sterile
2	IQ35F150B	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").Straight Tip.Bentson (23 cm).....Fixed Core.PTFE Coated.....Sterile
3	IQ35F150BC	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").Straight Tip.Bentson C (15 cm).....Fixed Core.PTFE Coated.....Sterile
4	IQ35F150BST	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").Straight Tip.Bentson ST (10 cm).....Fixed Core.PTFE Coated.....Sterile
5	IQ35F150J15	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").15 mm J-Tip.Standard.....Fixed Core.PTFE Coated.....Sterile
6	IQ35F150J105	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").1.5 mm J-Tip.Standard.....Fixed Core.PTFE Coated.....Sterile

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7	IQ35F150J105K	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").1.5 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
8	IQ35F150J105RS	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").1.5 mm J-Tip.Rosen.....Fixed Core.PTFE Coated....Sterile
9	IQ35F150J105RSK	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").1.5 mm J-Tip.Rosen.....Fixed Core.PTFE Coated....Sterile
10	IQ35F150J105S	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").1.5 mm J-Tip/ Straight.Double Ended.....Fixed Core.PTFE Coated....Sterile
11	IQ35F150J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
12	IQ35F150J3F	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").3 mm J-Tip.Firm.....Fixed Core.PTFE Coated....Sterile
13	IQ35F150J3K	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile-Multipack
14	IQ35F150J3S	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").3 mm J-Tip/ Straight.Double Ended.....Fixed Core.PTFE Coated....Sterile

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15	IQ35F150J3SHD	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").3 mm J-Tip/ Straight.Heavy Duty..Double Ended...Fixed Core.PTFE Coated....Sterile
16	IQ35F150J3SK	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").3 mm J□Tip/ Straight.Double Ended.....Fixed Core.PTFE Coated....Sterile-Multipack
17	IQ35F150J6	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").6 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
18	IQ35F150NLLL	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").Straight Tip.Newton LLLT (23.5 cm).....Fixed Core.PTFE Coated....Sterile
19	IQ35F150NLLT	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").Straight Tip.Newton LLT (18.5 cm).....Fixed Core. PTFE Coated....Sterile
20	IQ35F150NLT	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").Straight Tip.Newton LT (13.5 cm).....Fixed Core. PTFE Coated....Sterile
21	IQ35F150S	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").Straight Tip.Standard.....Fixed Core.PTFE Coated....Sterile

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22	IQ35F180B	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").Straight Tip.Bentson (23 cm).....Fixed Core.PTFE Coated....Sterile
23	IQ35F180BC	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").Straight Tip.Bentson C (15 cm).....Fixed Core.PTFE Coated....Sterile
24	IQ35F180BK	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").Straight Tip.Bentson (23 cm).....Fixed Core.PTFE Coated....Sterile-Multipack
25	IQ35F180BST	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").Straight Tip.Bentson ST (10 cm).....Fixed Core.PTFE Coated....Sterile
26	IQ35F180J15	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").15 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
27	IQ35F180J1O5	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").1.5 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
28	IQ35F180J1O5RS	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").1.5 mm J-Tip.Rosen.....Fixed Core.PTFE Coated....Sterile

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29	IQ35F180J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
30	IQ35F180J3F	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").3 mm J-Tip.Firm.....Fixed Core.PTFE Coated....Sterile
31	IQ35F180J3K	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile-Multipack
32	IQ35F180J3S	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").3 mm J-Tip/ Straight.Double Ended.....Fixed Core. PTFE Coated....Sterile
33	IQ35F180J6F	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).180 cm (71").6 mm J-Tip.Firm.....Fixed Core.PTFE Coated....Sterile
34	IQ35F210J105	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).210 cm (83").1.5 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
35	IQ35F210J105F	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).210 cm (83").1.5 mm J-Tip.Firm.....Fixed Core.PTFE Coated....Sterile

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36	IQ35F210J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).210 cm (83").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
37	IQ35F210J3K	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).210 cm (83").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile-Multipack
38	IQ35F220J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).220 cm (87").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated. PTFE Coated...Sterile
39	IQ35F260B	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).260 cm (102").Straight Tip.Bentson (23 cm) Exchange.....Fixed Core.PTFE Coated....Sterile
40	IQ35F260BST	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).260 cm (102").Straight Tip.Bentson ST (10 cm) Exchange..... Fixed Core.PTFE Coated.PTFE Coated...Sterile
41	IQ35F260J105	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).260 cm (102").1.5 mm J-Tip.Standard Exchange.....Fixed Core. PTFE Coated....Sterile
42	IQ35F260J105F	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).260 cm (102").1.5 mm J-Tip.Firm.....Fixed Core.PTFE Coated....Sterile

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43	IQ35F260J1O5RS	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).260 cm (102").1.5 mm J-Tip.Rosen Exchange.....Fixed Core. PTFE Coated....Sterile
44	IQ35F260J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).260 cm (102").3 mm J-Tip.Standard Exchange.....Fixed Core. PTFE Coated....Sterile
45	IQ35F260J3K	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).260 cm (102").3 mm J-Tip.Standard Exchange.....Fixed Core.PTFE Coated....Sterile-Multipack
46	IQ35F260J3S	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).260 cm (102").3 mm J-Tip/ Straight.Double Ended.....Fixed Core.PTFE Coated.PTFE Coated...Sterile
47	IQ35F260S	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).260 cm (102").Straight Tip.Standard Exchange.....Fixed Core. PTFE Coated....Sterile
48	IQ35F80B	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).80 cm (31.5").Straight Tip.Bentson (23 cm).....Fixed Core.PTFE Coated....Sterile
49	IQ35F80J1O5RS	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).80 cm (31.5").1.5 mm J-Tip.Rosen.....Fixed Core.PTFE Coated....Sterile

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50	IQ35F80J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).80 cm (31.5").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
51	IQ38F150B	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).150 cm (59").Straight Tip.Bentson (23 cm).....Fixed Core.PTFE Coated....Sterile
52	IQ38F150BC	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).150 cm (59").Straight Tip.Bentson C (15 cm).....Fixed Core.PTFE Coated....Sterile
53	IQ38F150J15	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).150 cm (59").15 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
54	IQ38F150J105RS	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).150 cm (59").1.5 mm J-Tip.Rosen.....Fixed Core.PTFE Coated....Sterile
55	IQ38F150J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).150 cm (59").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
56	IQ38F150J3F	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).150 cm (59").3 mm J-Tip.Firm.....Fixed Core.PTFE Coated....Sterile

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57	IQ38F150J3S	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).150 cm (59").3 mm J-Tip/ Straight.Double Ended.....Fixed Core. PTFE Coated.....Sterile
58	IQ38F150J6	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).150 cm (59").6 mm J-Tip.Standard.....Fixed Core.PTFE Coated.....Sterile
59	IQ38F150J6K	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).150 cm (59").6 mm J-Tip.Standard.....Fixed Core.PTFE Coated.....Sterile-Multipack
60	IQ38F150S	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).150 cm (59").Straight Tip.Standard.....Fixed Core.PTFE Coated.....Sterile
61	IQ38F180J3F	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).180 cm (71").3 mm J-Tip.Firm.....Fixed Core.PTFE Coated.....Sterile
62	IQ38F180J6F	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).180 cm (71").6 mm J-Tip.Firm Body.....Fixed Core.PTFE Coated.....Sterile
63	IQ38F260J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).260 cm (102").3 mm J-Tip.Standard Exchange.....Fixed Core.PTFE Coated.....Sterile

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64	IQ38F260J3F	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).260 cm (102").3 mm J-Tip.Firm.....Fixed Core.PTFE Coated....Sterile
65	IQ38F260S	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).260 cm (102").Straight Tip.Standard Exchange.....Fixed Core.PTFE Coated....Sterile
66	IQ38F50J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).50 cm (20").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
67	IQ38F80J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.038" (0.97 mm).80 cm (31.5").3 mm J-Tip.Standard.....Fixed Core.PTFE Coated....Sterile
68	IQR35F150B	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").Straight Tip.Bentson (23 cm).....Fixed Core.PTFE Coated...Ringmaster™.Sterile
69	IQR35F150BST	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").Straight Tip.Bentson Short Taper.....Fixed Core.PTFE Coated...Ringmaster™.Sterile
70	IQR35F150J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").3 mm J-Tip.Standard J 3.0 mm Tip.....Fixed Core. PTFE Coated...Ringmaster™.Sterile

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71	IQR35F150J3F	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").3 mm J-Tip.Firm Body J 3.0 mm Tip.....Fixed Core.PTFE Coated...Ringmaster™.Sterile
72	IQR35F150J3S	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).150 cm (59").3 mm J-Tip/ Straight.Double Ended J 3.0 mm / Straight Tip.....Fixed Core.PTFE Coated...Ringmaster™.Sterile
73	IQR35F260J3	InQwire Diagnostic Guide Wires	InQwire®.Guide Wire.0.035" (0.89 mm).260 cm (102").3 mm J-Tip.Standard J 3.0 mm Tip Exchange..... Fixed Core.PTFE Coated...Ringmaster™.Sterile
74	IQA500	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).145 cm (57").3 mm J-Tip.Amplatz.....Fixed Core.PTFE Coated.PTFE Coated...Sterile
75	IQA501	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).180 cm (71").3 mm J-Tip.Amplatz.....Fixed Core.PTFE Coated.PTFE Coated...Sterile
76	IQA502	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).260 cm (102").3 mm J-Tip.Amplatz Exchange...Exchange..Fixed Core.PTFE Coated.PTFE Coated...Sterile
77	IQA503	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.038" (0.97 mm).145 cm (57").3 mm J-Tip.Amplatz.....Fixed Core.PTFE Coated.PTFE Coated...Sterile

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78	IQA504	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.038" (0.97 mm).180 cm (71").3 mm J-Tip.Amplatz.....Fixed Core.PTFE Coated.PTFE Coated...Sterile
79	IQA509	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).260 cm (102").Straight Short (1.0 cm) Tip.Amplatz Exchange..Short (1.0 cm).Short Taper Exchange.1.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
80	IQA510	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.038" (0.97 mm).260 cm (102").Straight Short (1.0 cm) Tip.Amplatz Exchange..Short (1.0 cm).Short Taper Exchange.1.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
81	IQA511	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).180 cm (71").Straight Short (1.0 cm) Tip.Amplatz..Short (1.0 cm).Short Taper.1.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
82	IQA512	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.038" (0.97 mm).180 cm (71").Straight Short (1.0 cm) Tip.Amplatz..Short (1.0 cm).Short Taper.1.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
83	IQA513	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).75 cm (29").Straight Short (1.0 cm) Tip.Amplatz..Short (1.0 cm).Short Taper.1.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile

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84	IQA517	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.038" (0.97 mm).145 cm (57").Straight (6.0 cm) Tip.Amplatz..6.0 cm..6.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
85	IQA518	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.038" (0.97 mm).145 cm (57").Straight Short (4.0 cm) Tip.Amplatz..Short (4.0 cm).Short Taper.4.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
86	IQA519	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.038" (0.97 mm).180 cm (71").Straight (6.0 cm) Tip.Amplatz..6.0 cm..6.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
87	IQA520	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.038" (0.97 mm).260 cm (102").Straight (6.0 cm) Tip.Amplatz Exchange..6.0 cm.Exchange.6.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
88	IQA521	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).75 cm (29").Straight Short (4.0 cm) Tip.Amplatz..Short (4.0 cm).Short Taper.4.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
89	IQA522	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).180 cm (71").Straight Short (4.0 cm) Tip.Amplatz..Short (4.0 cm).Short Taper.4.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile

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Supplementary Information to CE 560101

Issued To:

**Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan
Utah
84095
USA**

#	Catalogue Number	Device Name	Model, Type
90	IQA523	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).145 cm (57").Straight (7.0 cm) Tip.Amplatz..7.0 cm..7.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
91	IQA524	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).145 cm (57").Straight Short (4.0 cm) Tip.Amplatz..Short (4.0 cm).Short Taper.4.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
92	IQA525	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).180 cm (71").Straight (7.0 cm) Tip.Amplatz..7.0 cm..7.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
93	IQA526	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).260 cm (102").Straight (7.0 cm) Tip.Amplatz Exchange..7.0 cm.Exchange.7.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
94	IQA527	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).145 cm (57").Straight Short (3.5 cm) Tip.Amplatz..Short (3.5 cm).Short Taper.3.5 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
95	IQA528	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.038" (0.97 mm).145 cm (57").Straight Short (3.5 cm) Tip.Amplatz..Short (3.5 cm).Short Taper.3.5 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile

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South Jordan
Utah
84095
USA**

#	Catalogue Number	Device Name	Model, Type
96	IQA563	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.035" (0.89 mm).75 cm (29").Straight (7.0 cm) Tip.Amplatz..7.0 cm..7.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile
97	IQA564	InQwire Amplatz Guide Wires	InQwire® Amplatz.Guide Wire.0.038" (0.97 mm).75 cm (29").Straight (6.0 cm) Tip.Amplatz..6.0 cm..6.0 cm.Fixed Core.PTFE Coated.PTFE Coated...Sterile

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1600 West Merit Parkway
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Utah
84095
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Certificate History

Date	Reference Number	Action
30 March 2010	10114148	First Issue – Classification change from IIa to III per 2007/47/EC
07 July 2010	10116686	Addition of alternative sterilization cycles at Sterigenics, Salt Lake City and Caridian BCT, Colorado and correction of a typing error on the catalog number listing.
17 August 2010	10117400	Outline the Bracketing of the Qualified Guide Wire Parameter Ranges to replace individual catalogue numbers with a table.
03 August 2011	10129932	Modifications to the ETO sterilization cycle for all catalogue numbers.
11 March 2015	10153259	Certificate renewal.
11 March 2016	10159617	Change affecting Tyvek® 1073B and Tyvek® 1059B packaging materials - All product codes are affected.
26 April 2017	10168199	The addition of InQwire® Amplatz Super Stiff Guide Wire product codes.
26 October 2017	8814857	Addition of alternate sterilization facility, Sterigenics Belgium (Petit-Rechain).
23 November 2017	8849372	Change in supplier from KOBUSCH (Bottom Web) and BEMIS/Perfecseal (Top Web) to AMCOR (Top and Bottom Web). Change to 100 micron PE Film (Top Web) and 2FS coated Tyvek (Bottom Web), and change in thermoforming process parameters.

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Date	Reference Number	Action
22 May 2018	8843518	Line extension by 3 new catalogue codes to the range of InQwire® Amplatz Super Stiff Guides Wires
08 February 2019	7780616	Traceable to NB 0086.
27 September 2019	9767469	Modification of ETO sterilization cycle at Sterigenics Belgium (Petit-Rechain).
16 December 2019	3058360	Reformat Product Table. Addition of alternative sterilization site: Sterigenics US LLC 5725 West Harold Gatty Drive Salt Lake City Utah 87116 USA
19 February 2020	9715255	Certificate Renewal
Current	3264850	Replacement of external Process Challenge Device (ePCD) for Merit Medical EO Cycle 17 at Sterigenics Petit Rechain, Belgium.

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