



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 031162 0001 Rev. 01

Manufacturer: **William Cook Europe ApS**
Sandet 6
4632 Bjaeverskov
DENMARK

Product: **Guidewires**
Vascular Wire Guides

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:G7_031162_0001_Rev.01

Report no.: 713197418

Valid from: 2020-12-17

Valid until: 2023-08-31

Date, 2020-12-17

Christoph Dicks
Head of Certification/Notified Body



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Model(s): see parameter

Parameter:

	Article/model numbers	Article/model name
1	THSCF-35-145-3-AUS1	Amplatz Ultra Stiff Wire Guide
2	THSCF-35-145-3-AUS2	Amplatz Ultra Stiff Wire Guide
3	THSCF-35-180-3-AUS1	Amplatz Ultra Stiff Wire Guide
4	THSCF-35-180-3-AUS2	Amplatz Ultra Stiff Wire Guide
5	THSCF-35-260-3-AUS1	Amplatz Ultra Stiff Wire Guide
6	THSCF-35-260-3-AUS2	Amplatz Ultra Stiff Wire Guide
7	THSCF-35-60-3-AUS1	Amplatz Ultra Stiff Wire Guide
8	THSCF-35-90-3-AUS1	Amplatz Ultra Stiff Wire Guide
9	THSCF-35-90-3-AUS2	Amplatz Ultra Stiff Wire Guide
10	THSF-35-145-AUS1	Amplatz Ultra Stiff Wire Guide
11	THSF-35-145-AUS2	Amplatz Ultra Stiff Wire Guide
12	THSF-35-180-AUS1	Amplatz Ultra Stiff Wire Guide
13	THSF-35-180-AUS2	Amplatz Ultra Stiff Wire Guide
14	THSF-35-260-AUS1	Amplatz Ultra Stiff Wire Guide
15	THSF-35-260-AUS2	Amplatz Ultra Stiff Wire Guide
16	THSF-35-90-AUS1	Amplatz Ultra Stiff Wire Guide
17	THSF-35-90-AUS2	Amplatz Ultra Stiff Wire Guide
18	TSCMG-35-145-4-7-LES	Lunderquist Extra Stiff Wire Guide
19	TSCMG-35-145-7-7-LES	Lunderquist Extra Stiff Wire Guide
20	TSCMG-35-145-4-3-LES	Lunderquist Extra Stiff Wire Guide
21	TSCMG-35-145-7-3-LES	Lunderquist Extra Stiff Wire Guide
22	TSCMG-35-180-4-3-LES	Lunderquist Extra Stiff Wire Guide
23	TSCMG-35-180-4-7-LES	Lunderquist Extra Stiff Wire Guide
24	TSCMG-35-180-7-3-LES	Lunderquist Extra Stiff Wire Guide
25	TSCMG-35-180-7-7-LES	Lunderquist Extra Stiff Wire Guide
26	TSCMG-35-260-7-LES	Lunderquist Extra Stiff Wire Guide
27	TSCMG-35-260-E-LESDC	Lunderquist Extra Stiff Wire Guide
28	TSCMG-35-260-LESDC	Lunderquist Extra Stiff Wire Guide
29	TSCMG-35-300-7-LES	Lunderquist Extra Stiff Wire Guide



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30	TSCMG-35-300-E-LESDC	Lunderquist Extra Stiff Wire Guide
31	TSCMG-35-300-LESDC	Lunderquist Extra Stiff Wire Guide
32	TSCMG-35-90-3-3-LES1	Lunderquist Extra Stiff Wire Guide
33	TSCMG-35-90-4-3-LES	Lunderquist Extra Stiff Wire Guide
34	TSCMG-35-90-4-7-LES	Lunderquist Extra Stiff Wire Guide
35	TSCMG-35-90-5-3-LES1	Lunderquist Extra Stiff Wire Guide
36	TSCMG-35-90-7-3-LES	Lunderquist Extra Stiff Wire Guide
37	TSCMG-35-90-7-7-LES	Lunderquist Extra Stiff Wire Guide
38	TSMG-35-145-4-LES	Lunderquist Extra Stiff Wire Guide
39	TSMG-35-145-7-LES	Lunderquist Extra Stiff Wire Guide
40	TSMG-35-180-4-LES	Lunderquist Extra Stiff Wire Guide
41	TSMG-35-180-7-LES	Lunderquist Extra Stiff Wire Guide
42	TSMG-35-260-LES	Lunderquist Extra Stiff Wire Guide
43	TSMG-35-300-LES	Lunderquist Extra Stiff Wire Guide
44	TSMG-35-90-3-LES1	Lunderquist Extra Stiff Wire Guide
45	TSMG-35-90-4-LES	Lunderquist Extra Stiff Wire Guide
46	TSMG-35-90-7-LES	Lunderquist Extra Stiff Wire Guide
47	TSMG-35-90-7-LES1	Lunderquist Extra Stiff Wire Guide