



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 039709 1317 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product:

**Catheters for Single Use
Guiding Catheters for Coronary and
Peripheral Use**

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. See also notes overleaf.

Report no.:

713180071

Valid from:

2020-03-18

Valid until:

2023-05-25

Date,

2020-03-18



Christoph Dicks

Head of Certification/Notified Body



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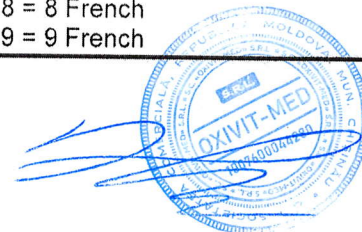
No. G7 039709 1317 Rev. 00

Model(s):

Zuma (6-9F) Guiding Catheter
Z2 (5-8F) Guiding Catheter
Launcher (5-8F) Guiding Catheter
5F Sherpa NX Active Guiding Catheter
6F Sherpa NX Active Guiding Catheter
6F Sherpa NX Balanced Guiding Catheter
7F Sherpa NX Balanced Guiding Catheter
8F Sherpa NX Balanced Guiding Catheter
6F Taiga Guiding Catheter

Parameter:

Model Number	Designation	Variables
<u>1 2XXXXXXX</u> 1.1 1.2 ZMYXXXXXX ZSYXXXXXX ZTYXXXXXX Z2YXXXXXX LAYXXXXXX SAYXXXXXX SBYXXXXXX TA6XXXXXX	First two digits designate the model of Guide Catheter (Example: LA8JR40SH). Z2 (5-8F) Guiding Catheter Launcher (5-8F) 5F Sherpa NX Active 6F Sherpa NX Active 6F Sherpa NX Balanced 7F Sherpa NX Balanced 8F Sherpa NX Balanced 6F Taiga Guiding Catheter	ZM: Zuma Guiding Catheter ZS: Zuma Flexible Segment ZT: Zuma Tungsten Ring Z2: Z2 Guiding Catheter LA: Launcher Guiding Catheter SA: Sherpa NX Active SB: Sherpa NX Balanced TA: Taiga Guiding Catheter
Y	Y designates the French Size	5 = 5 French 6 = 6 French 7 = 7 French 8 = 8 French 9 = 9 French





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XXXXXXX	XXXXXXX designates the curve shape and size*	Major curves: JL = Judkins Left JR = Judkins Right AL = Amplatz Left AR = Amplatz Right MB = Multiple Purpose FL = Femoral Left FR = Femoral Right HS = Hockey Stick DC = Doctor's Choice SR = Short right SL = Short Left IMA = International Mammary Artery EBU = Extra Backup LCB = Left Coronary Bypass RCB = Right Coronary Bypass JCL = Judkins Coronary Left JCR = Judkins Coronary Right SAR = Short Amplatz Right SAL = Short Amplatz Left SCR = Shepard's Cook Right RDC = Renal Double Curve PK1 = Renal Curve MPH = Hockey Stick MP1 = Multipurpose Curve MB1 = Multipurpose Curve MB2 = Multipurpose Curve MAC = Multi-Aortic Curve ARANI, BONRT, BOUL, ECR, MRADIAL, LARA, RAD, 3DRIGHT, 3DRC, IMA, CHAMP, EL GAMAL, NOTO, MPIK, MBXT, MP2, MRADIAL, MULTIA, PK1W, MPHK, RDCK, RICA, RRAD, RB, RBU, PER, STRAIGHT, WHB, RDND1K, IMAK
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*Curve Sizes: Vary from 0.5 to 6.5 for different curves.

Other Size Variables:

- **Shaft length:** 30 – 130 cm (Letter added to item number), Standard Length is 100 cm. Suffix: A = 110cm, B = 95cm, C = 51cm, D = 90cm, E = 85cm, F = 80cm, H = 70cm, I = 65cm, J = 60cm, K = 55cm, L = 50cm, M = 88cm, N = 30cm, Q = 93cm, R = 75cm, T = 35cm, U = 40cm, V = 45cm, W = 47cm.

Shaft length:

- 5F & 6F Launcher guide: 30 - 130 cm
- 7F & 8F Launcher guide: 30 - 120 cm
- 5F Sherpa NX /6F Sherpa NX Active & Balanced: 30 - 130 cm
- 7F & 8F Sherpa: 30 - 120 cm
- ZUMA, ZUMA II, and Taiga: 30 - 120 cm

Sideholes: Optional (SH added to item number).

