Greatbatch Medical

DECLARATION OF CONFORMITY

Percutaneous Introducer Systems and Safety Needles

Revision	Description
A	[redacted]
B	[redacted]
C	[redacted]
D	[redacted]

Declaration of Conformity

Manufacturer:	Greatbatch Medical 2300 Berkshire Lane North Minneapolis, MN 55441 USA Phone: 763-951-8181 Fax: 763-559-0148
European Representative:	MPS Medical Product Service GmbH Borngasse 20 D-35619 Braunfels GERMANY Phone: +49/6442/962073 Fax: +49/6442/962074
Product:	See Product Listing in Appendices A – G.
Conformity Assessment:	MDD 93/42/EEC, Annex II
Classification:	Class IIa per MDD Annex IX Rule 7

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. Greatbatch Medical is exclusively responsible for this declaration. All supporting documentation is retained under the premises of the manufacturer.

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Germany Identification Number: 0123
Annex II.3 Certificate Number:	G1 070692 0028
Products with Annex II.4 certificates have a separate Declaration to Annex II.4	
Start of CE-marking:	April 15, 2004
Place of Issue:	Greatbatch Medical 2300 Berkshire Lane North Minneapolis, MN 55441 USA
Signature / Date:	 / 17 April 2020 Mathew Pexa Sr. Manager, Design Assurance and Regulatory Affairs

Appendix A – [redacted] Products Covered

Greatbatch Medical Part Number	Product Family Name
[redacted]	[redacted]

Appendix B – [redacted] Products Covered

Greatbatch Medical Part Number	Product Family Name
[redacted]	[redacted]

Appendix C – [redacted] Products Covered

Greatbatch Medical Part Number	Product Family Name
[redacted]	[redacted]

Appendix D – [redacted] Products Covered

Greatbatch Medical Part Number	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

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Appendix E – [redacted] Products Covered

Greatbatch Medical Part Number	Product Family Name
[redacted]	[redacted]

Greatbatch Medical Part Number	Product Family Name
[redacted]	[redacted]

Greatbatch Medical Part Number	Product Family Name
[redacted]	[redacted]

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Appendix F – LI Plus Products Covered

Greatbatch Medical Part Number	Biotronik S.E. & Co. KG Model Number for Product Manufactured in Minneapolis, MN	Biotronik S.E. & Co. KG Model Number for Product Manufactured in Tijuana, Mexico
10773-009	370700	417669
10773-010	370701	417670
10773-011	370702	417671
10773-012	370703	417672
10773-013	370704	417673
10773-014	370705	417674
10773-015	370706	417675

Appendix G – [redacted] Products Covered

Greatbatch Medical Part Number	Product Family Name
[redacted]	[redacted]