

DECLARATION OF CONFORMITY

Percutaneous Introducer Systems and Safety Needles

Revision	Description
A	
В	
C	
D	



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
European Representative.	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
	above mentioned products meet the provisions of the es. Greatbatch Medical is exclusively responsible for this tained under the premises of the manufacturer.
Notified Body:	TÜV SÜD Product Service GmbH
,	Ridlerstrasse 65
	80339 München
	Germany Identification Number: 0123
	Identification Number: 0125
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
	Matlew Le
Signature / Date:	/ 17 April 2020

Mathew Pexa

Sr. Manager, Design Assurance and Regulatory Affairs



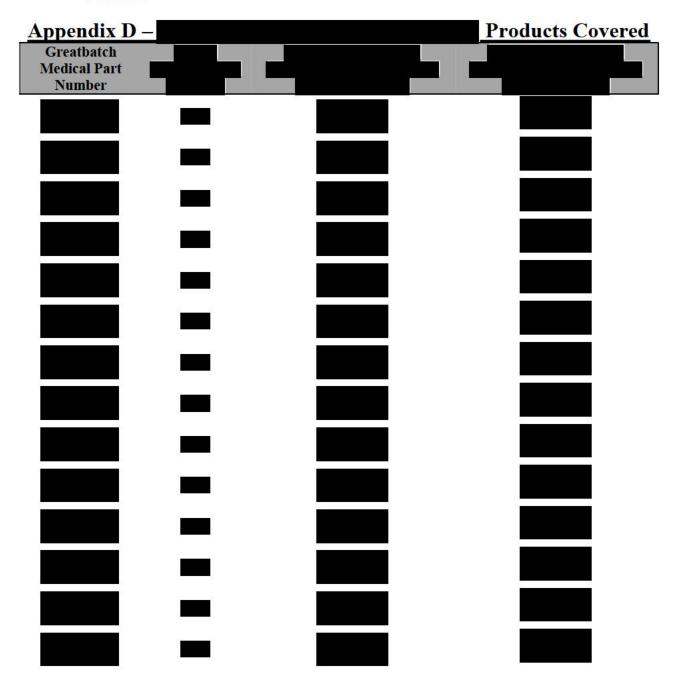
Appendix A –	Products Covered
Greatbatch Medical Part Number	Product Family Name





Appendix C –	Products Covered
Greatbatch Medical Part Number	Product Family Name







Products Covered
Product Family Name



Greatbatch Medical Part Number	Product Family Name





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 –	Products Covered
Greatbatch Medical Part Number	Product Family Name