

## Declaration of Conformity

Manufacturer: Greatbatch Medical  
2300 Berkshire Lane North  
Minneapolis, MN 55441  
Phone: (763) 951-8181  
Fax: (763) 559-0148

European Representative: Medical Device Safety Service GmbH  
Schiffgraben 41  
30175 Hannover  
Germany  
Phone: +49 511 6262 8630  
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Products: See Attached

Conformity Assessment: AIMD 90/385/EEC, Annex II

Classification: Active Implantable

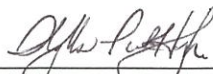
We, the manufacturer, herewith declare that the above mentioned products meet the provisions of the Council Directive 90/385/EEC for active implantable medical devices. All supporting documentation is retained under the premises of the manufacturer.

Notified Body: TUV SUD Product Services GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Identification Number: 0123

EC Certificate: Annex II excluding (4), I1 17 08 70692 021  
Annex II(4), I7 17 11 70692 022

Start of CE-marking: April 18<sup>th</sup>, 1996

Place of Issue: Greatbatch Medical  
2300 Berkshire Lane North  
Minneapolis, MN 55441  
USA

Signature /Date:  12 January 2018

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Phyllis Piet-Hughes  
Sr. Manager, Regulatory Affairs, Clinical &  
Compliance

Greatbatch Medical Model Number	Description	Length
<b>Myopore Bipolar Sutureless Pacing Lead</b>		
511210	IS-1 Bipolar Sutureless Myocardial Pacing Lead	25 cm
511211	IS-1 Bipolar Sutureless Myocardial Pacing Lead	35 cm
511212	IS-1 Bipolar Sutureless Myocardial Pacing Lead	54 cm
<b>MyoDex Steroid-Eluting Bipolar Sutureless Myocardial Pacing Lead</b>		
1084T-25	IS-1 Bipolar Sutureless Myocardial Pacing Lead	25 cm
1084T-35	IS-1 Bipolar Sutureless Myocardial Pacing Lead	35 cm
1084T-54	IS-1 Bipolar Sutureless Myocardial Pacing Lead	54 cm
<b>Lead Adapters</b>		
501203	5mm Unipolar Lead to IS-1 Unipolar Connector	13 cm
501204	6mm Unipolar Lead to IS-1 Unipolar Connector	13 cm
501205	5mm Bipolar Dual Lead to IS-1 Bipolar Connector	15 cm
501206	3.2mm Bipolar Lead to IS-1 Bipolar Connector	14 cm
501214	3.2 mm Bipolar Lead Extender to IS-1 Bipolar Connector	47 cm
<b>Cap and Sleeve Kit</b>		
501207	Contains the following components: <ul style="list-style-type: none"> <li>• Terminal Pin Cap, 5mm/6mm</li> <li>• Terminal Pin Cap, 3.2mm</li> <li>• Adapter Sleeve, 3.2mm to 5mm</li> <li>• Adapter Sleeve, 5mm to 6mm</li> <li>• Connector Pin Adapter</li> <li>• Hex Wrench/Set Screw Assembly</li> </ul>	Not Applicable
<b>FasTac Flex Steerable Lead Implant Tool</b>		
6201FAS	FasTac Flex Steerable Lead Implant Tool	44 cm