## **DECLARATION OF CONFORMITY**

Legal Manufacturer:

Boston Scientific Corporation One Boston Scientific Place

Natick

MA 01760-1537

**USA** 

**Manufacturing Site(s):** 

**Boston Scientific Corporation** 

780 Brookside Drive Spencer, IN 47460

USA

**EU** Authorized

Representative:

Boston Scientific International S.A.

55 avenue des Champs Pierreux

TSA 51101

92729 NANTERRE CEDEX

**FRANCE** 

**Product:** 

Retrievals Family of Devices (See Attachment I)

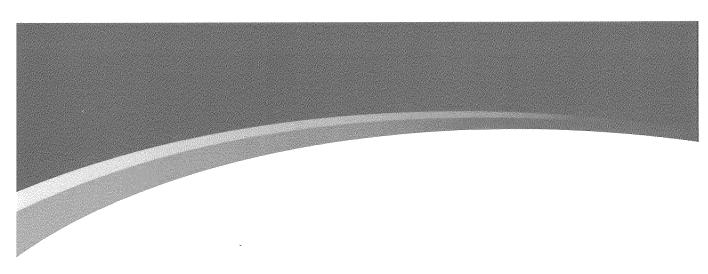
(Technical File # 90480632)

**Classification:** 

Class IIa devices in conformity with Annex IX, Rule 5 of the

**MDD** 

Boston Scientific
Sub Report – Declaration of Conformity
EC Declaration of Conformity Retrievals Family of Devices
90453142 Rev/Ver AB
Page 1 of 4



We declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices as amended by Directive 2007/47/EC. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal Manufacturer.

**Notified Body:** 

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg

Germany

Identification number 0197

Date of First CE Marking: Not Required as product is currently commercialized.

Signature, Date of Issue:

Name: Jeff Biggers (or Designee)

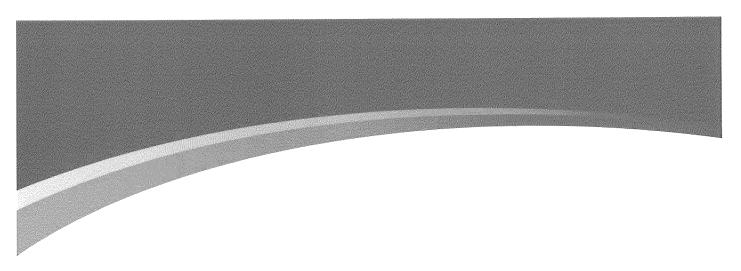
Title: Vice President, Quality Assurance Endosurgery

Signature: Date: 8Mai 2010

Name: Rob Miragliuolo (or Designee)

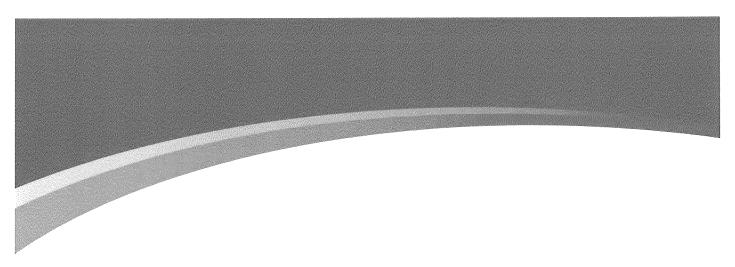
Title: Vice President, Regulatory Affairs Endosurgery

Signature: Blent + Minglish Date: March 04, 2010



## ATTACHMENT I

UPN	Product Description
M0063401210	Bagley Stone Retrieval Helical Basket
M0063401210 M0063401220	
M0063301040	
M0063301040 M0063301050	
M0063301030 M0063301060	Gemini Stone Retrieval Paired Wire/Helical Basket
M0063301070	
M0063301080	
M0063301090	
M0063301100	
M0063301110	
M0063301120	
M0063301140	
M0063301150	
M0063301160	
M0063302040	
M0063302050	
M0063302060	
M0063302080	
M0063302090	
M0063302100	
M0063302110	
M0063302120	
M0063302140	
M0063302150	
M0063303040	
M0063303060	
M0063303070	



## ATTACHMENT I (CONTINUED)

UPN	Product Description
M0063203000	Leslie Parachute Stone Retrieval Device
M0063203010	
M0063203020	
M0063203030	
M0063801000	Segura Hemisphere Stone Retrieval Basket
M0063801020	
M0063801060	
M0063801070	
M0063801100	
M0063801120	
M0063801160	
M0063801180	
M0063801190	
M0068404120	LithoCatch
M0063204000	Graspit Urological Grasping Forceps
M0063204010	
M0063204020	
M0063204030	
M0063701000	Stone Retrieval Grasping Forceps
M0063701010	
M0063701100	
M0063701110	
M0063701140	
M0063701150	
M0063701180	
M0063701190	
M0063701220	
M0063701230	