

Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Boulevard
Covington, Georgia 30014
USA



DECLARATION OF CONFORMITY

DC Number: DC030065

Revision: 10

C. R. Bard, Inc.

located at:
8195 Industrial Boulevard
Covington, Georgia 30014 USA,

does hereby declare that the Bard® Nitinol Guidewire, which consists of the device catalog number(s) referenced on the attached list, meets the provisions and requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD). The CE marking has been affixed in accordance with article 17 of the MDD.

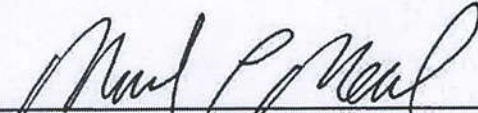
Classification (MDD, Annex IX, Rule 7): Class IIa meeting Annex II and receipt of CE Certificate from Notified Body.

Notified Body:

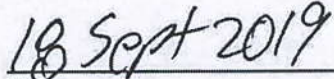
BSI Product Services (ID # 2797)
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

C. R. Bard, Inc.'s Authorized Representative is:

BD Switzerland Sàrl
Terre Bonne Park - A4
Route de Crassier 17
1262 Eysins,
Switzerland



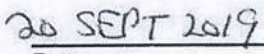
VP Quality Assurance, Mark Neal



Date



Director Regulatory Affairs, Michele Davis



Date

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
150NFS35	NiCore™ Nitinol/Nitinol Guidewire, .035 in., 3cm, 150cm, Standard, Straight	45623	General-purpose non-vascular guidewire
150NFA35	NiCore™ Nitinol/Nitinol Guidewire, .035 in., 3cm, 150cm, Standard, Angled	45623	General-purpose non-vascular guidewire
150NBS35	NiCore™ Nitinol/Nitinol Guidewire, .035 in., 8cm, 150cm, Standard, Bentson	45623	General-purpose non-vascular guidewire
150NSS35	NiCore™ Nitinol/Nitinol Guidewire, .035 in., 3cm, 150cm, Stiff, Straight	45623	General-purpose non-vascular guidewire
150NSA35	NiCore™ Nitinol/Nitinol Guidewire, .035 in., 3cm, 150cm, Stiff, Angled	45623	General-purpose non-vascular guidewire
150NFS38	NiCore™ Nitinol/Nitinol Guidewire, .038 in., 3cm, 150cm, Standard, Straight	45623	General-purpose non-vascular guidewire
150NFA38	NiCore™ Nitinol/Nitinol Guidewire, .038 in., 3cm, 150cm, Standard, Angled	45623	General-purpose non-vascular guidewire
150NBS38	NiCore™ Nitinol/Nitinol Guidewire, .038 in., 8cm, 150cm, Standard, Bentson	45623	General-purpose non-vascular guidewire
150NSS38	NiCore™ Nitinol/Nitinol Guidewire, .038 in., 3cm, 150cm, Stiff, Straight	45623	General-purpose non-vascular guidewire
150NSA38	NiCore™ Nitinol/Nitinol Guidewire, .038 in., 3cm, 150cm, Stiff, Angled	45623	General-purpose non-vascular guidewire

Development Released

DECLARATION OF CONFORMITY

DC Number: DC030065 Revision: 10

REVISION HISTORY

<u>REV. #</u>	<u>CR #</u>	<u>DESCRIPTION</u>
0	03-4432#46	Created Declaration of Conformity for Nitinol Core Guidewire, Technical File #54, per Project 4432.
1	03-4432#91	Updated Declaration of Conformity and removed InLay Codes so that the Declaration of Conformity is for the Guidewires only. The InLay codes were added to the Declarations of Conformity for Technical Files 5, 38 and 40.
2	TechFile-BUD#75	Added the "NiCore™" name to the Nitinol Guidewires per Project 03-4814.
3	03-4648#65	Added the product codes for the U-Nite™ Guidewire (250NSS25, 250NSS35, 250NSS38, 250NSA35, 250NSA38).
4	Tech File #317	Converted to BMD format and added GMDN code and description.
5	TechFile#606	Updated with approval date after March 21, 2010 to provide evidence of compliance to the MDD updates.
6	BM-COV-CR-01227	Updated document to reflect FM0301166 Rev 2.
7	BM-COV-CR-05535	Updated rule from 6 to 7 per MDD, Annex IX, as these devices are "surgically invasive, short term use". Updated document to reflect FM0301166 Rev 3.
8	BM-COV-CR-06714	Updated to remove U-Nite™ Guidewires (250NSS25, 250NSS35, 250NSS38, 250NSA35, 250NSA38) as they have been discontinued per CSA-03-5206-0002. Updated GMDN term to align with database term.
9	BM-PROJ-CR-20466	Updated document to reflect FM0301166 Rev. 4
10	BM-COV-CR-07737	Updated to reflect FM0301166 Revision 5 which included update to Authorized Representative Information and approval personnel.

Signature Manifest

Document Number: DC030065

Revision: 10

Title: Declaration of Conformity for Technical File 65 - Nitinol Guidewire

All dates and times are in Eastern Standard Time.

DoC Update - TF37, 50 and 65

Doc Control Check

Name/Signature	Title	Date	Meaning/Reason
DEEPAN KARNAN (DKARNAN)	R&D Engineer Temp - HCL		
Jaimie Mowers (JMOWERS)	QA Specialist/Doc Control		
Jessica Latimore (JLATIMORE)	Training Coordinator III		
Rachel Harms (RHARMS)	Documentation Specialist		
Sasha Sims (SSIMS)	Document Control Lead		
Yasmin Roman (YROMAN)	Doc. Control Analyst		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II	13 Nov 2019, 08:53:47 AM	Approved

Assign Approvers/Modify

Name/Signature	Title	Date	Meaning/Reason
DEEPAN KARNAN (DKARNAN)	R&D Engineer Temp - HCL		
Jaimie Mowers (JMOWERS)	QA Specialist/Doc Control		
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Yasmin Roman (YROMAN)	Doc. Control Analyst		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II	13 Nov 2019, 08:54:49 AM	Complete

Review/Approve

Name/Signature	Title	Date	Meaning/Reason
Dana Abdelal (DABDELAL)	RA Specialist	20 Nov 2019, 10:34:59 AM	Approved

DC Final Review

Name/Signature	Title	Date	Meaning/Reason
Mark Tremblay (10287705)	Quality Systems Manager	03 Dec 2019, 12:28:16 PM	Complete

CR Final Release

Name/Signature	Title	Date	Meaning/Reason
Mark Tremblay (10287705)	Quality Systems Manager	03 Dec 2019, 12:28:34 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Dana Abdelal (DABELLAL)	RA Specialist	03 Dec 2019, 12:28:35 PM	Email Sent



gần nhất nhập.
hại lý chôn đố
Tuy linh hoạt của
quỹ một lần
sự tiện lợi của việc

việc diện kiến phải một tay
một lần và sự dễ dàng của
sự tiện lợi của việc sử dụng

Wojobroja

Max Corp

Development Released

