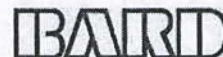




Hard Medical Division  
C. R. Bard, Inc.  
8195 Industrial Blvd.  
Covington, Georgia 30014  
USA



### DECLARATION OF CONFORMITY

DC Number: DC030082

Revision: 7

C. R. Bard, Inc.

located at:  
8195 Industrial Blvd.  
Covington, Georgia 30014  
USA,

does hereby declare that the Skylite™ Nitinol Tipless Baskets, 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 5): Class 1, Sterile meeting Annex V and receipt of CE Certificate from the Notified Body.

Notified Body:

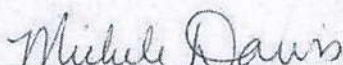
BSI Product Services (ID # 2797)  
Say Building  
John M. Keynesplein 9  
1066 EP Amsterdam  
The Netherlands

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

Becton Dickinson Ireland Ltd.  
Donore Road, Drogheda  
Co. Louth, A92 YW26  
Ireland

  
\_\_\_\_\_  
VP Quality Assurance, Mark Neal

19 Nov 2021  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
VP Regulatory Affairs, Michele Davis

22 Nov 2021  
\_\_\_\_\_  
Date

### DECLARATION OF CONFORMITY

DC Number: DC030082

Revision: 7

PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
041900	SkyLite™ 1.9 Fr. Nitinol Tipless Basket, 120cm x 12mm	46452	Biliary/Urinary Stone Retrieval Basket, Single Use
042400	SkyLite™ 2.4 Fr. Nitinol Tipless Basket, 120cm x 12mm	46452	Biliary/Urinary Stone Retrieval Basket, Single Use
043000	SkyLite™ 3.0 Fr. Nitinol Tipless Basket, 120cm x 12mm	46452	Biliary/Urinary Stone Retrieval Basket, Single Use

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### DECLARATION OF CONFORMITY

DC Number: DC030082

Revision: 7

#### REVISION HISTORY

<u>REV. #</u>	<u>CR #</u>	<u>DESCRIPTION</u>
0	BM-PROJ-CR-05329	Original per Project 5589.
1	BM-PROJ-CR-05742	GMDN code was transposed. It was listed as 46542 and should have been 46452.
2	BM-PROJ-CR-08675	Updated per Project 5818, added 3.0 Fr Basket
3	BM-PROJ-CR-09204	GMDN code was listed as 46542 and has been corrected to 46452. Updated to match certification scope, therefore changed from Annex II to Annex V.
4	BM-PROJ-CR-19272	Updated DoC to remove reference to directive 64/65/EEC relating to medicinal products
5	BM-PROJ-CR-20469	Updated document to reflect FM0301166 Rev. 4.
6	BM-COV-CR-07734	Updated to reflect FM0301166 Revision 5 which included update to Authorized Representative Information and approval personnel.
7	BM-PROJ-CR-30936	Updated to reflect FM0301166 Revision 6 which included update to Authorized Representative Information and approval personnel.

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### Signature Manifest

Document Number: DC030082

Revision: 7

Title: Declaration of Conformity for Technical File 82 - Nitinol Tipless Baskets

All dates and times are in Eastern Standard Time.

### BM-PROJ-CR-30936 DoC Updates

#### Doc Control Check

Name/Signature	Title	Date	Meaning/Reason
DEEPAN KARNAN (DKARNAN)	R&D Engineer Temp - HCL		
Jaimie Mowers (JMOWERS)	Sr Quality System Specialist		
Jessica Latimore (JLATIMORE)	Document Control Coordinator		
Rachel Harms (RHARMS)	Documentation Specialist		
Sasha Sims (SSIMS)	Document Control Lead		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II	24 Nov 2021, 01:12:00 PM	Approved

#### Assign Approvers/Modify

Name/Signature	Title	Date	Meaning/Reason
DEEPAN KARNAN (DKARNAN)	R&D Engineer Temp - HCL		
Jaimie Mowers (JMOWERS)	Sr Quality System Specialist		
Jessica Latimore (JLATIMORE)	Document Control Coordinator		
Rachel Harms (RHARMS)	Documentation Specialist		
Sasha Sims (SSIMS)	Document Control Lead		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II	24 Nov 2021, 01:12:51 PM	Complete

#### Review/Approve

Name/Signature	Title	Date	Meaning/Reason
Hannah Kriscovich (HKRISCOVICH)	CLDP Engineer - RA Spec 1	24 Nov 2021, 01:25:50 PM	Approved

#### DC Final Review

Name/Signature	Title	Date	Meaning/Reason
Jaimie Mowers (JMOWERS)	Sr Quality System Specialist		
Jessica Latimore (JLATIMORE)	Document Control Coordinator		
Sasha Sims (SSIMS)	Document Control Lead		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		In Process
Rachel Harms (RHARMS)	Documentation Specialist	29 Nov 2021, 08:21:29 PM	Complete

#### CR Final Release

Name/Signature	Title	Date	Meaning/Reason

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Name/Signature	Title	Date	Meaning/Reason
Jaimie Mowers (JMOWERS)	Sr Quality System Specialist		
Jessica Latimore (JLATIMORE)	Document Control Coordinator		
Sasha Sims (SSIMS)	Document Control Lead		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Rachel Harms (RHARMS)	Documentation Specialist	29 Nov 2021, 08:21:52 PM	Approved

**Notification**

Name/Signature	Title	Date	Meaning/Reason
Hannah Kriscovich (HKRISCOVICH)	CLDP Engineer - RA Spec 1	29 Nov 2021, 08:21:53 PM	Email Sent

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