DoC Number/Revision: 10523855 rev. 6
GMDN Code: 17846
Product Family: Vista Brite Tip
Product Group: Catheter, intravascular, guiding

CFF 10255063 rev 6
Only native file to be used

Declaration of Conformity (DoC)

Manufacturer: **Name:** Cordis Corporation

Address: 14201 North West 60th Avenue
Miami Lakes
Florida, FL 33014
USA

Full Quality Assurance Certificate Number CE 00340.

Authorized Representative:

Name: Cordis Cashel

Address: Cahir Road,
Cashel,
Co. Tipperary. Ireland

Products/Model No:

The **Cordis 6F 0.070" Vista Brite Tip Guiding Catheter and Cordis 6F 0.070" Envoy Guiding Catheter** are classified as Class III, per Rule Number 6 of Annex IX of the Medical Device Council Directive 93/42/EEC. This declaration applies to the following product codes bearing the CE marking. **Design Examination Certificate CE 69002.**

Cordis

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Catalogue Numbers: 670-XXX-XX(B)

General Designation: XXX – XXX – XXX

X	X	X	-	X	X	X	-	X	X	X
1	2	3		4	5	6		7	8	9

Number / Designation		Limitation
1	Outer Diameter (last Digit of French Size)	Will always be **6** French
2,3	Lumen Size (last two digits in thousandths of an inch)	0.065 – 0.075 inches
4,5,6	Configuration 000-299 Standard (subassembly) design 300-599 Design Variation 1 600-899 Design Variation 2 900-999 Design variation 3 / Overflow	Odd numbers contain a side hole Even numbers do not contain a side hole
7, 8	Length (last two digits in cm)	50 – 125 cm
In addition, digits 8 or 9 may contain a single letter code: For example, E – Econopack L – Long Brite Tip N – Guiding Catheter with an introducer		
In addition, digit 9 (i.e. "B") is sometimes used and indicates extra backup devise		

Modified Standards: SMXXXX and SMXXXXX

Lot number(s)

This Declaration of Conformity applies to all lot numbers

REPUBLICA MOLDOVA S.R.L. Clasdac IDNO 1005600034230 SOCIETATEA COMERCIALĂ

Cordis
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

CFF 10255063 rev 6
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DoC Number/Revision: 10523855 rev. 6
GMDN Code: 17846
Product Family: Vista Brite Tip
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Declaration of Conformity (DoC)

Manufacturing site:

The **Cordis 6F 0.070" Vista Brite Tip Guiding Catheter and Cordis 6F 0.070" Envoy Guiding Catheter** are manufactured at the following site:

Cordis de México S.A.de C.V.
Calle Circuito Interior Norte #1820
Parque Industrial Salvarcar
Ciudad Juarez, Chihuahua
CP 32574
México

Declaration: We, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of Directive 93/42/EEC as last amended.
In order to affix CE marking, Cordis Corporation has followed the procedure relating to the EC declaration of conformity set out in Annex II, Clause 4 of the Directive 93/42/EEC as last amended. The full quality system has been certified by British Standards Institution (BSI) a Notified Body authorized to carry out such assessments and having the designation 0086.

Approved by:

Mayra Cisneros
Manager, Regulatory Affairs
Cordis Corporation

(Signature) 06/07/13 (Date)

REPUBLICA MOLDOVA S.R.L. Clasdac IDNO 1005600034230 SOCIETATEA COMERCIALĂ