Cordis Corporation
14201 Northwest 60th Avenue
Miami Lakes, FL 33014
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100568032 Attachment 1 – Declaration of Conformity (MDD and MDR), Rev 1
Only Native File to be used
DoC Number/Revision: 10118148 Rev. 15

DECLARATION OF CONFORMITY

MDD: We, Cordis Cashel, declare that the products covered in this Declaration of Conformity meet the provision of the Council Directive 93/42/EEC for Medical Devices as amended by 2007/47/EC and as transposed in the national laws of the Member States.

Technical Documentation Number	10118148
Manufacturer's Name	Cordis Cashel
Manufacturer's Address	Cahir Road, Cashel, Co. Tipperary, Ireland
Authorized Representative's Name and Address	Not Applicable
Notified body's Name and Identification Number	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identification Number: 2797
CE Certificate Number	CE 560271
Product Name	Cordis OPTEASE® Retrievable Vena Cava Filter
Basic UDI-DI	Not Applicable
Product Code(s) and Description	See table below
Intended Purpose	The OPTEASE Retrievable Vena Cava Filter is indicated for the prevention of pulmonary embolism (PE) via percutaneous placement in the IVC in patients considered at high risk of PE.
Classification and Rule	Classified as Class III, per Annex IX, Rule Number 8.
Single Registration Number	Not Applicable
Common Specifications	Not Applicable
Where appropriate, add applicable Union legislation	Not Applicable

DEVICE CODE	PRODUCT DESCRIPTION			
	FRENCH SIZE	LENGTH INTRODUCER SYSTEM	LENGTH GUIDEWIRE	LENGTH VESSEL DILATOR
466-F210A	6F	55cm	150cm	66cm
466-F210B	6F	90cm	260cm	101cm
466-F210AF	6F	55cm	150cm	66cm
466-F210AJ	6F	55cm	150cm	66cm
466-F210BJ	6F	90cm	260cm	101cm

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.07 14:02:44 EEST
Reason: MoldSign Signature
Location: Moldova

Cordis
A Cardinal Health company

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DECLARATION OF CONFORMITY	
Conformity assessment	ANNEX VII of the Medical Device Directive 93/42/EEC of 14 June 1993 as amended by the 2007/47/EC.
GMDN Code	44864 - Vena cava filter, temporary/permanent

SIGNATURE SECTION				
This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.				
Place of Issue	**Cordis Cashel, Cahir Road, Cashel, Co. Tipperary, Ireland**			
Signature			**Date**	16-Feb-2021
Title/Position	Nicola Parry, Principal Specialist, Regulatory Affairs			
Signature	LR	*Electronically signed by: Linda Ruedy Reason: Approved Date: Feb 15, 2021 16:39 PST*	**Date**	Feb 15, 2021
Title/Position	Linda Ruedy, Director Regulatory Affairs			
Signature	Matt Hedrick	*Electronically signed by: Matt Hedrick Reason: Approved Date: Feb 15, 2021 13:33 EST*	**Date**	Feb 15, 2021
Title/Position	Matt Hedrick, Director QRA			

Physical Manufacturer name:	Cardinal Health Mexico 244 S. De RL De CV
Physical address of Manufacturer:	Santiago Troncoso #808 Parque Industrial Salvarcar Ciudad Juarez, Chihuahua C.P. 32574 México