By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 560271**

Issued To: **Cordis Cashel**
Cahir Road
Cashel
Tipperary
Ireland

In respect of:

Cordis OptEase Retrievable Vena Cava Filter

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.07 14:01:47 EEST
Reason: MoldSign Signature
Location: Moldova

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2010-03-10** Date: **2018-04-27** Expiry Date: **2023-05-07**

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Supplementary Information to CE 560271

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Cordis OptEase Retrievable Vena Cava Filter

Catalogue Number	Description
466-F210A	OptEase Vena Cava Filter system for use with 55 cm Introducer
466-F210B	OptEase Vena Cava Filter system for use with 90 cm Introducer
466-F210AF	OptEase Vena Cava Filter system for use with 55 cm Introducer, Femoral access
466-F210AJ	OptEase Vena Cava Filter system for use with 55 cm Introducer, Jugular access
466-F210BJ	OptEase Vena Cava Filter system for use with 90 cm Introducer, Jugular and Antecubital access

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Certificate History

Date	Reference Number	Action
10 March 2010	10115393	First issue based on CE 68460.
25 June 2010	10116851	Clarification to the Cordis Cashel address.
22 April 2013	10141159	Certificate renewal.
24 May 2013	10141180	Review of change of Stopcock supplier and material resin change.
29 August 2013	10143364	Addition of Nitinol Devices and Components, Costa Rica, as an alternative manufacturing site for the filter component.
29 October 2015	10157163	Addition of product codes with modified packaging configuration; 466-F210AF, 466-F210AJ and 466-F210BJ.
04 February 2016	10160465	Change affecting DuPont Tyvek 1073B packaging material – all product codes are affected.
10 October 2017	8787830	Manufacturing transfer from building 1 to building 2 at Cordis de Mexico.
Current	8903131	Certificate renewal.

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