By Royal Charter

EC Design-Examination Certificate

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

No. **CE 552677**

Issued To: **Cordis Corporation**
14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA

In respect of:

Cordis EXOSEAL® Vascular Closure Device

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 2797):

Digitally signed by Ostapciuc Alexandr
Date: 2023.07.08 14:27:12 EEST
Reason: MoldSign Signature
Location: Moldova

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2010-04-30** Date: **2020-10-20** Expiry Date: **2024-05-26**

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Supplementary Information to CE 552677

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Product: Cordis EXOSEAL® Vascular Closure Device

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
EX500CE	Cordis EXOSEAL® 5F Vascular Closure Device	5F	The **EXOSEAL®** Vascular Closure Device is indicated for femoral artery puncture site closure, reducing time to hemostasis and ambulation in patients who have undergone diagnostic or interventional procedures using a standard corresponding French size vascular sheath introducer with up to a 12 cm working length.	Class III Implantable
EX600CE	Cordis EXOSEAL® 6F Vascular Closure Device	6F		Class III Implantable
EX700CE	Cordis EXOSEAL® 7F Vascular Closure Device	7F		Class III Implantable

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Certificate History

Date	Reference Number	Action
30 April 2010	10109023	First Issue.
08 December 2010	10118867	Addition 5 and 7F sizes of the vascular closure device as line extensions to the EXOSEAL product family.
16 April 2015	10154598	Certificate renewal.
07 March 2018	8801989	Added new E-Beam sterilization site Steri-Tek (Fremont, CA).
06 March 2019	7780552	Traceable to NB 0086.
29 November 2019	9714378	Certificate Renewal. Administrative update to product table format.
Current	3255820	Shelf-life extension from 2 years to 4 years for all catalogue numbers.

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Supplementary Information to CE 552677 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to: **Cordis Corporation**
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Date: 22 February 2023

Changes Approved:

Date	Reference Number	Action
22 February 2022	3560096	Change of the E-beam dosage determination method and consequent change of the sterilization dose. Change of the sterilization loading configuration.
22 February 2023	3772571	Addition of sterilization site – Addition of alternate IFU paper

Inspiring trust for a more resilient world.

22 February 2023

Cordis Corporation
14201 North West 60th Avenue
Miami Lakes
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33014
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 552677	93/42/EEC Annex II Section 4	3772571	Addition of sterilization site – Addition of alternate IFU paper

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com bsigroup.nl