EC Design-Examination Certificate

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

No. **CE 704856**

Issued To: **Cardinal Health**
5452 Betsy Ross Drive
Santa Clara
California
95054
USA

In respect of:

MYNX CONTROL™ 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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-07-22** Date: **2020-02-21** Expiry Date: **2024-05-26**

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Supplementary Information to CE 704856

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Product: MYNX CONTROL™ Vascular Closure Device

Catalog Number	Device Name	Model, Type	Intended purpose per IFU	Classification
MX6760E	MYNX CONTROL™ Vascular Closure Device	6/7F	Indicated for use to seal femoral arterial access sites while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5F, 6F or 7F procedural sheath.	Class III
MX5060E	MYNX CONTROL™ Vascular Closure Device	5F		

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Certificate History

Date	Reference Number	Action
22 July 2019	9699483	First Issue
Current	3124135	Added new supplier SinoPEG for hydrogel sealant component.

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By Royal Charter

Supplementary Information to CE 704856 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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Date: 08 October 2021

Changes Approved:

Date	Reference Number	Action
08 October 2021	3540189	Qualification of alternative syringes supplied by SOL-Millennium Medical Inc. for finished devices sterilized by Steri-Tek at Fremont, California.

Inspiring trust for a more resilient world.

08 October 2021

Cardinal Health
5452 Betsy Ross Drive
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95054
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 704856	93/42/EEC Annex II Section 4	3540189	Qualification of alternative syringes supplied by SOL-Millennium Medical Inc. for finished devices sterilized by Steri-Tek at Fremont, California.

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,

Gary Slack
Senior Vice President, Medical Devices

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