By Royal Charter

EC Design-Examination Certificate

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

No. **CE 617228**

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

In respect of:

MynxGrip 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 0086):

Gary Fenton, Global Assurance Director

First Issued: **26 August 2014** Date: **14 October 2014** Expiry Date: **25 August 2019**

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EC Design-Examination Certificate

Supplementary Information to CE 617228

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Product: MynxGrip Vascular Closure Device

Description	Catalog Number
6F/7F MynxGrip Vascular Closure Device	MX6721
5F MynxGrip Vascular Closure Device	MX5021

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Certificate History

Date	Reference Number	Action
26 August 2014	10149665	First issue. Transfer (from another Notified Body) and Renewal.
14 October 2014	10151586	Change legal manufacturer name from AccessClosure, Inc. to Cardinal Health. Minor changes to IFU and labeling including company name change, change of EU Representative, and IFU changes for clarity and listing additional identified risks.

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