By Royal Charter

# EC Design-Examination Certificate

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

**No.** **CE 508048**

Issued To: **Johnson & Johnson MEDICAL GmbH**
**Robert-Koch-Strasse 1**
**Norderstedt**
**22851**
**Germany**

In respect of:

**ABSOLOK EXTRA Ligature Clips**

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):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 November 2006** Date: **01 November 2016** Expiry Date: **30 May 2021**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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**Supplementary Information to CE 508048**

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**ABSOLOK EXTRA Ligature Clips**

| Product Code | Product Name | Clip Size | Quantity of Clips | Magazine Color Code |
|---|---|---|---|---|
| AP100 | ABSOLOK EXTRA Ligature Clips | Small | 10 | Blue |
| AP200 | ABSOLOK EXTRA Ligature Clips | Medium | 10 | White |
| AP201 | ABSOLOK EXTRA Ligature Clips | Medium | 5 | White |
| AP202 | ABSOLOK EXTRA Ligature Clips | Medium | 2 | White |
| AP300 | ABSOLOK EXTRA Ligature Clips | Medium Large | 10 | Green |
| AP301 | ABSOLOK EXTRA Ligature Clips | Medium Large | 5 | Green |
| AP302 | ABSOLOK EXTRA Ligature Clips | Medium Large | 2 | Green |
| AP306 | ABSOLOK EXTRA Ligature Clips | Medium Large | 6 | Green |
| AP400 | ABSOLOK EXTRA Ligature Clips | Large | 10 | Yellow |
| AP401 | ABSOLOK EXTRA Ligature Clips | Large | 5 | Yellow |
| AP402 | ABSOLOK EXTRA Ligature Clips | Large | 2 | Yellow |
| AP403 | ABSOLOK EXTRA Ligature Clips | Large | 3 | Yellow |
| AP406 | ABSOLOK EXTRA Ligature Clips | Large | 6 | Yellow |

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## Certificate History

| Date | Reference Number | Action |
|---|---|---|
| 01 November 2006 | 10078407 | Transferred from another Notified Body. |
| 15 April 2008 | 10096381 | Reissued due to change of company name. |
| 24 October 2011 | 10130151 | Certificate renewal. |
| 10 May 2016 | 10162422 | Change in labelling for the removal of special storage conditions and update to the IFU content.<br>Administrative modifications. |
| 01 November 2016 | 10162836 | Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®).<br>Renewal.<br>Administrative update to supplementary page details.<br>Removal of product codes AP101, AP203, AP303, AP404. |

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