

# EC Design-Examination Certificate

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

**No.**

**CE 668802**

Issued To:

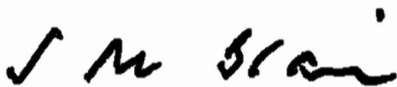
**Establishment Labs S.A.  
Coyol Free Zone & Business Park Building  
4th Street, Building B15  
Alajuela  
Costa Rica**

In respect of:

**Motiva Implants<sup>®</sup> Anatomical TrueFixation<sup>™</sup>, Sterile Silicone Breast Implants.**

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: **2018-06-06**

Date: **2018-06-06**

Expiry Date: **2023-06-05**

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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.

# EC Design-Examination Certificate

## Supplementary Information to CE 668802

Issued To:

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### Anatomical TrueFixation™ SmoothSilk® Full

| Product Code         | Description  |
|----------------------|--|
| ASFF-44 to ASFF-54   | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, without Qid™. Projection: High (Full-Full).   |
| ASMF-44 to ASMF-54   | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, without Qid™. Projection: High (Medium-Full). |
| ASLF-44 to ASLF-54   | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, without Qid™. Projection: High (Low-Full).    |
| ASFF-44Q to ASFF-54Q | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, with Qid™. Projection: High (Full-Full).      |
| ASMF-44Q to ASMF-54Q | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, with Qid™. Projection: High (Medium-Full).    |
| ASLF-44Q to ASLF-54Q | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, with Qid™. Projection: High (Low-Full).       |

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### Anatomical TrueFixation™ SmoothSilk® Corsé

| Product Code                    | Description  |
|---------------------------------|--|
| ASFC-54, ASFC-58 and ASFC-60    | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, without Qid™. Projection: Super High (Full-Corsé).    |
| ASMC-54 to ASMC-62              | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, without Qid™. Projection: Super High (Medium- Corsé). |
| ASLC-54 to ASLC-60              | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, without Qid™. Projection: Super High (Low-Corsé).     |
| ASFC-54Q, ASFC-58Q and ASFC-60Q | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, with Qid™. Projection: Super High (Full-Corsé).       |
| ASMC-54Q to ASMC-62Q            | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, with Qid™. Projection: Super High (Medium- Corsé).    |
| ASLC-54Q to ASLC-60Q            | Anatomical, SmoothSilk®, ProgressiveGel™ Plus, with Qid™. Projection: Super High (Low-Corsé).        |

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## Certificate History

| Date    | Reference Number | Action       |
|---------|------------------|--------------|
| Current | 8689325          | First issue. |

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