

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® Anatomical TrueFixation™, 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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2018-06-06**

Date: **2019-02-25**

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 668802

Issued To:

**Establishment Labs S.A.
Coyol Free Zone & Business Park Building
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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

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