

EC Design-Examination Certificate

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

No.**CE 596345**

Issued To:

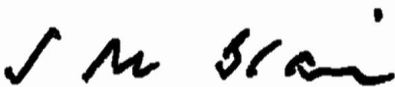
**Establishment Labs S.A.
Coyol Free Zone & Business Park Building
4th Street, Building B15
Alajuela
Costa Rica**

In respect of:

Sterile Silicone Breast Implants Motiva Implant Matrix

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: **2016-09-01**Date: **2017-05-24**Expiry Date: **2022-05-24**

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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.

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Supplementary Information to CE 596345

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1. Motiva Implants Matrix® Ergonomix™ SilkSurface® and VelvetSurface®

Product Codes	DESCRIPTION (Shape, Texture, Gel, w or w/o RFID, Projection)
ERSM-105 to ERSM-525	Round, SilkSurface®, ProgressiveGel™ Ultima™ without Qid™.
ERSD-135 to ERSD-625	Projection:
ERSF-145 to ERSF-775	Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE)
ERSC-180 to ERSC-1050	
ERSM-105Q to ERSM-525Q	Round, SilkSurface®, ProgressiveGel™ Ultima™ with Qid™.
ERSD-135Q to ERSD-625Q	Projection:
ERSF-145Q to ERSF-775Q	Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE)
ERSC-180Q to ERSC-1050Q	

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Product Codes	DESCRIPTION (Shape, Texture, Gel, w or w/o RFID, Projection)
ERVM-105 to ERVM-525	Round, VelvetSurface®, ProgressiveGel™ Ultima™ without Qid™. Projection: Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE´)
ERVD-135 to ERVD-625	
ERVF-145 to ERVF-775	
ERVC-180 to ERVC-1050	
ERVM-105Q to ERVM-525Q	Round, VelvetSurface®, ProgressiveGel™ Ultima™ with Qid™. Projection: Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE´)
ERVD-135Q to ERVD-625Q	
ERVF-145Q to ERVF-775Q	
ERVC-180Q to ERVC-1050Q	

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Product Codes	DESCRIPTION (Shape, Texture, Gel, w or w/o RFID, Projection)
EOSM-26 to EOSM-32	Oval, SilkSurface®, ProgressiveGel™ Ultima™ without Qid™.
EOSD-35 to EOSD-43	Projection:
EOSF-39 to EOSF-61	Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE´)
EOSC-45 to EOSC-78	
EOSM-26Q to EOSM-32Q	Oval, SilkSurface®, ProgressiveGel™ Ultima™ with Qid™.
EOSD-35Q to EOSD-43Q	Projection:
EOSF-39Q to EOSF-61Q	Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE´)
EOSC-45Q to EOSC-78Q	

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Product Codes	DESCRIPTION (Shape, Texture, Gel, w or w/o RFID, Projection)
EOVM-26 to EOVM-32	Oval, VelvetSurface®, ProgressiveGel™ Ultima™ without Qid™.
EOVD-35 to EOVD-43	Projection: Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE´)
EOVF-39 to EOVF-61	
EOVC-45 to EOVC-78	
EOVM-26Q to EOVM-32Q	Oval, VelvetSurface®, ProgressiveGel™ Ultima™ with Qid™.
EOVD-35Q to EOVD-43Q	Projection: Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE´)
EOVF-39Q to EOVF-61Q	
EOVC-45Q to EOVC-78Q	

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2. Motiva Implant Matrix® SilkSurface® or SmoothSilk®

Product Codes	DESCRIPTION (Shape, Texture, Gel, w or w/o RFID, Projection)
RSM-105 to RSM-525	Round, SilkSurface® or SmoothSilk®, ProgressiveGel™ without Qid™.
RSD-135 to RSD-625	Projection:
RSF-145 to RSF-775	Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE)
RSC-180 to RSC-1050	
RSM-105Q to RSM-525Q	Round, SilkSurface® or SmoothSilk®, ProgressiveGel™ with Qid™.
RSD-135Q to RSD-625Q	Projection:
RSF-145Q to RSF-775Q	Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE)
RSC-180Q to RSC-1050Q	

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3. Motiva Implant Matrix® SilkSurface® Plus

Product Codes	DESCRIPTION (Shape, Texture, Gel, w or w/o RFID, Projection)
RSM-105+ to RSM-525+	Round, SilkSurface®, ProgressiveGel™ Plus, without Qid™.
RSD-135+ to RSD-625+	Projection: Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE)
RSF-145+ to RSF-775+	
RSC-180+ to RSC-1050+	
RSM-105+Q to RSM-525+Q	Round, SilkSurface®, ProgressiveGel™ Plus, with Qid™.
RSD-135+Q to RSD-625+Q	Projection: Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE)
RSF-145+Q to RSF-775+Q	
RSC-180+Q to RSC-1050+Q	
RSC-180+Q to RSC-1050+Q	

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4. Motiva Implant Matrix® VelvetSurface® Plus

Product Codes	DESCRIPTION (Shape, Texture, Gel, w or w/o RFID, Projection)
RVM-105+ to RVM-525+	Round, VelvetSurface®, ProgressiveGel™ Plus, without Qid™.
RVD-135+ to RVD-625+	Projection: Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE)
RVF-145+ to RVF-775+	
RVC-180+ to RVC-1050+	
RVM-105+Q to RVM-525+Q	Round, VelvetSurface®, ProgressiveGel™ Plus, with Qid™. Projection: Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE)
RVD-135+Q to RVD-625+Q	
RVF-145+Q to RVF-775+Q	
RVC-180+Q to RVC-1050+Q	

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5. Motiva Implant Matrix® VelvetSurface®

Product Codes	DESCRIPTION (Shape, Texture, Gel, w or w/o RFID, Projection)
RVM-105 to RVM-525	Round, VelvetSurface®, ProgressiveGel™, without Qid™.
RVD-135 to RVD-625	Projection: Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE)
RVF-145 to RVF-775	
RVC-180 to RVC-1050	
RVM-105Q to RVM-525Q	Round, VelvetSurface®, ProgressiveGel™ with Qid™.
RVD-135Q to RVD-625Q	Projection: Low (MINI), Moderate (DEMI), High (FULL), Super High (CORSE)
RVF-145Q to RVF-775Q	
RVC-180Q to RVC-1050Q	

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Certificate History

Date	Reference Number	Action
01 September 2016	10162799	First issue. Transfer from another Notified Body.
24 May 2017	10170431	Certificate renewal.

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