EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 745219 R000

Manufacturer: Establishment Labs S.A.

Address:
Coyol Free Zone & Business Park Building
4th Street, Building B15
Alajuela
20113
Costa Rica

Single Registration Number: CR-MF-000008155

EU Authorised Representative: Emergo Europe

Address:
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-05-23** Date: **2022-05-23** Expiry Date: **2025-05-22**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 745219 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:
The breast implants are used for breast reconstruction (primary and revision): to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast anomaly, as well as revision surgery to correct or improve the results of a previous breast reconstruction surgery.

Risk Classification: Class III

Type: MDN 1104, MDS 1005

1. **Motiva Implant Matrix® SilkSurface® or SmoothSilk®**

Catalogue/reference	Description (shape, texture, gel, w or w/o RFID, projection)	Basic UDI-DI
RSM-105+ to RSM-525+ RSD-135+ to RSD-625+ RSF-145+ to RSF-775+ RSC-180+ to RSC-1050+	Round, SilkSurface® or SmoothSilk®, ProgressiveGel® PLUS, without microtransponder Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161SilkPlusS4
RSM-105+Q to RSM-525+Q RSD-135+Q to RSD-625+Q RSF-145+Q to RSF-775+Q RSC-180+Q to RSC-1050+Q	Round, SilkSurface® or SmoothSilk®, ProgressiveGel® PLUS with Qid® Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161SilkPlusQKU
RSM-105+Z to RSM-525+Z RSD-135+Z to RSD-625+Z RSF-145+Z to RSF-775+Z RSC-180+Z to RSC-1050+Z	Round SilkSurface® or SmoothSilk®, ProgressiveGel® PLUS with Zen® Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161SilkPlusZen8Z

First Issued: **2022-05-23** Date: **2022-05-23** Expiry Date: **2025-05-22**

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 745219 R000

2. Motiva Implant Matrix® VelvetSurface®

Catalogue/reference	Description (shape, texture, gel, w or w/o RFID, projection)	Basic UDI-DI
RVM-105+ to RVM-525+ RVD-135+ to RVD-625+ RVF-145+ to RVF-775+ RVC-180+ to RVC-1050+	Round, VelvetSurface®, ProgressiveGel® PLUS, without microtransponder Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161VelvetPlus62
RVM-105+Q to RVM-525+Q RVM-135+Q to RVD-625+Q RVF-145+Q to RVF-775+Q RVC-180+Q to RVC-1050+Q	Round, VelvetSurface®, ProgressiveGel® PLUS with Qid® Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161VelvetPlusQHA
RSM-105+Z to RSM-525+Z RSD-135+Z to RSD-625+Z RSF-145+Z to RSF-775+Z RSC-180+Z to RSC-1050+Z	Round VelvetSurface®, ProgressiveGel® PLUS with Zen® Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161VelvetPlusZenEJ

3. Motiva Implant Matrix® Ergonomics® SilkSurface® or SmoothSilk®

Catalogue/reference	Description (shape, texture, gel, w or w/o RFID, projection)	Basic UDI-DI
ERSM-105 to ERSM-525 ERSD-135 to ERSD-625 ERSF-145 to ERSF-775 ERSC-180 to ERSC-1050	Round, SilkSurface® or SmoothSilk®, ProgressiveGel® Ultima®, without microtransponder Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161ErgoroundR5
ERSM-105Q to ERSM-525Q ERSD-135Q to ERSD-625Q ERSF-145Q to ERSF-775Q ERSC-180Q to ERSC-1050Q	Round, SilkSurface® or SmoothSilk®, ProgressiveGel® Ultima® with Qid® Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161ErgoroundQYN

First Issued: **2022-05-23** Date: **2022-05-23** Expiry Date: **2025-05-22**

...making excellence a habit.™

Catalogue/reference	Description (shape, texture, gel, w or w/o RFID, projection)	Basic UDI-DI
ERSM-105Z to ERSM-525Z ERSD-135Z to ERSD-625Z ERSF-145Z to ERSF-775Z ERSC-180Z to ERSC-1050Z	Round SilkSurface® or SmoothSilk®, ProgressiveGel® Ultima® with Zen® Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161ErgoroundZen8Y

4. Motiva Implant Matrix® Ergonomics® VelvetSurface®

Catalogue/reference	Description (shape, texture, gel, w or w/o RFID, projection)	Basic UDI-DI
ERVM-105 to ERVM-525 ERVD-135 to ERVD-625 ERVF-145 to ERVF-775 ERVC-180 to ERVC-1050	Round, VelvetSurface®, ProgressiveGel® Ultima®, without microtransponder Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161ErgoVelvetM5
ERVM-105Q to ERVM-525Q ERVD-135Q to ERVD-625Q ERVF-145Q to ERVF-775Q ERVC-180Q to ERVC-1050Q	Round, VelvetSurface®, ProgressiveGel® Ultima® with Qid® Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161ErgoVelvetQZ2
ERVM-105Z to ERVM-525Z ERVD-135Z to ERVD-625Z ERVF-145Z to ERVF-775Z ERVC-180Z to ERVC-1050Z	Round VelvetSurface®, ProgressiveGel® Ultima® with Zen® Projection: Low (Mini), Moderate (Demi), High (Full), Super High (Corsé)	7445161ErgoVelvetZenPE

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 745219 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3392458	Issued

First Issued: **2022-05-23** Date: **2022-05-23** Expiry Date: **2025-05-22**

...making excellence a habit.™