

# EU Technical Documentation Assessment Certificate

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

## MDR 746961 R000

**Manufacturer:** Eurosilicone SAS

**Address:**

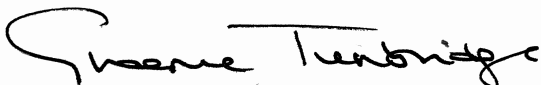
Z.I de la Peyrolière  
B.P. 68  
Apt Cédex  
84402  
France

**Single Registration Number:** FR-MF-000008947

**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 Issue Date: **2022-09-24**

Current Issue Date: **2022-09-24**

Starting Validity Date: **2022-09-24**

Expiry Date: **2027-09-23**

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**Device Schedule:**

**Intended Purpose as per the Instructions for Use:**

The Micro Textured Anatomical Breast Implant is intended for breast reconstruction surgery.

**Basic UDI-DI:** 037004697 A2001LK

**Risk Classification:** Class III Implantable

**Type** (Codes as per (EU) 2017/2185): MDN 1104

Product Reference	Description (Height, Projection)
MIA-HR1/135	Luna XT Micro Textured Anatomical Breast Implant Full Height, Low Projection
MIA-HR1/155	
MIA-HR1/185	
MIA-HR1/215	
MIA-HR1/245	
MIA-HR1/275	
MIA-HR1/315	
MIA-HR1/345	
MIA-HR1/400	
MIA-HR1/450	



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Product Reference	Description (Height, Projection)
MIA-HR2/165	Luna XT Micro Textured Anatomical Breast Implant Full Height, Moderate Projection
MIA-HR2/190	
MIA-HR2/215	
MIA-HR2/245	
MIA-HR2/275	
MIA-HR2/310	
MIA-HR2/345	
MIA-HR2/390	
MIA-HR2/440	
MIA-HR2/500	
MIA-HR2/575	
MIA-HR2/655	
MIA-HR2/710	
MIA-HR3/190	Luna XT Micro Textured Anatomical Breast Implant Full Height, High Projection
MIA-HR3/220	
MIA-HR3/250	
MIA-HR3/295	
MIA-HR3/330	
MIA-HR3/370	
MIA-HR3/415	
MIA-HR3/460	
MIA-HR3/505	
MIA-HR3/580	
MIA-HR3/645	
MIA-HR3/720	
MIA-HR3/775	



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Product Reference	Description (Height, Projection)
MIA-MR1/125	Luna XT Micro Textured Anatomical Breast Implant Moderate Height, Low Projection
MIA-MR1/140	
MIA-MR1/160	
MIA-MR1/195	
MIA-MR1/215	
MIA-MR1/245	
MIA-MR1/280	
MIA-MR1/320	
MIA-MR1/360	
MIA-MR1/405	
MIA-MR2/155	Luna XT Micro Textured Anatomical Breast Implant Moderate Height, Moderate Projection
MIA-MR2/175	
MIA-MR2/195	
MIA-MR2/230	
MIA-MR2/255	
MIA-MR2/290	
MIA-MR2/330	
MIA-MR2/375	
MIA-MR2/415	
MIA-MR2/465	
MIA-MR2/530	
MIA-MR2/595	
MIA-MR2/655	



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Product Reference	Description (Height, Projection)
MIA-MR3/175	Luna XT Micro Textured Anatomical Breast Implant Moderate Height, High Projection
MIA-MR3/205	
MIA-MR3/235	
MIA-MR3/275	
MIA-MR3/310	
MIA-MR3/345	
MIA-MR3/395	
MIA-MR3/440	
MIA-MR3/475	
MIA-MR3/545	
MIA-MR3/610	
MIA-MR3/685	
MIA-MR3/735	
MIA-LR1/110	Luna XT Micro Textured Anatomical Breast Implant Low Height, Low Projection
MIA-LR1/130	
MIA-LR1/145	
MIA-LR1/175	
MIA-LR1/200	
MIA-LR1/230	
MIA-LR1/265	
MIA-LR1/305	
MIA-LR1/345	
MIA-LR1/385	



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Product Reference	Description (Height, Projection)
MIA-LR2/135	Luna XT Micro Textured Anatomical Breast Implant Low Height, Moderate Projection
MIA-LR2/160	
MIA-LR2/190	
MIA-LR2/215	
MIA-LR2/245	
MIA-LR2/280	
MIA-LR2/320	
MIA-LR2/355	
MIA-LR2/405	
MIA-LR2/440	
MIA-LR3/160	Luna XT Micro Textured Anatomical Breast Implant Low Height, High Projection
MIA-LR3/190	
MIA-LR3/215	
MIA-LR3/260	
MIA-LR3/290	
MIA-LR3/330	
MIA-LR3/385	
MIA-LR3/415	
MIA-LR3/480	
MIA-LR3/525	



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### 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	3409578	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation 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.