

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants

**G&G Biotechnology Ltd.
4 Ben Gurion Street
Haifa, 3541415
Israel**

for the scope

**B-Lite Light Weight Breast Implants
(see attachment)**

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven
that the design meets the requirements according to

Annex II – Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

This certificate is only valid in connection with a valid
mdc certificate according to Annex II – excluding section 4 for the
above mentioned products.

| | |
|------------------|------------------|
| Valid from | 2018-08-20 |
| Valid until | 2023-08-19 |
| Registration no. | D1302000007 |
| Report no. | P17-00963-101186 |
| Stuttgart | 2018-08-20 |



Head of Certification Body



Attachment of the certificate

No. D1302000007

Date 2018-08-20

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| Product category | Product | Class |
|--|-------------------------------------|-------|
| Anatomical breast implant, round base, single lumen, with B-Lite gel filler, extra high profile and fine-textured surface | SL Style 15637-xxxLW25 (xxx=85-810) | III |
| Anatomical breast implant, round base , single lumen, with B-Lite gel filler, high profile and fine-textured surface | SL Style 15636-xxxLW25 (xxx=70-670) | III |
| Anatomical breast implant, round base, single lumen, with B-Lite gel filler, high profile with Microthane® covered surface | SL Style 30636-xxxLW25 (xxx=70-670) | III |
| Anatomical breast implant, round base, single lumen, with B-Lite gel filler, low profile and fine-textured surface | SL Style 15634-xxxLW25 (xxx=45-385) | III |
| Anatomical breast implant, round base, single lumen, with B-Lite gel filler, moderate profile and fine-textured surface | SL Style 15635-xxxLW25 (xxx=60-525) | III |
| Anatomical breast implant, round base, single lumen, with B-Lite gel filler, moderate profile with Microthane® covered surface | SL Style 30635-xxxLW25 (xxx=60-525) | III |
| Anatomical breast implant, round base single lumen, with B-Lite gel filler, extra high profile and Microthane® covered surface | SL Style 30637-xxxLW25 (xxx=85-810) | III |
| Anatomical breast implant, round base, single lumen, with B-Lite gel filler, low profile and Microthane® covered surface | SL Style 30634-xxxLW25 (xxx=45-385) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, extra high profile and fine-textured surface | SL Style 15647-xxxLW25 (xxx=75-750) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, high profile and fine-textured surface | SL Style 15646-xxxLW25 (xxx=65-615) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, low profile and fine-textured surface | SL Style 15644-xxxLW25 (xxx=45-360) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, moderate profile and fine-textured surface | SL Style 15645-xxxLW25 (xxx=55-490) | III |



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| Product category | Product | Class |
|---|-------------------------------------|-------|
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, extra high profile and Microthane® covered surface | SL Style 30647-xxxLW25 (xxx=75-750) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, extra high profile and textured surface | SL Style 20647-xxxLW25 (xxx=75-750) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, high profile and Microthane® covered surface | SL Style 30646-xxxLW25 (xxx=65-615) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, high profile and textured surface | SL Style 20646-xxxLW25 (xxx=65-615) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, low profile and Microthane® covered surface | SL Style 30644-xxxLW25 (xxx=45-360) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, low profile and textured surface | SL Style 20644-xxxLW25 (xxx=45-360) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, moderate profile and textured surface | SL Style 20645-xxxLW25 (xxx=55-490) | III |
| Anatomical breast implant, short base, single lumen, with B-Lite gel filler, moderate profile and Microthane® covered surface | SL Style 30645-xxxLW25 (xxx=55-490) | III |
| Anatomical breast implant, single lumen, with B-Lite gel filler, round base, extra high profile and textured surface | SL Style 20637-xxxLW25 (xxx=85-810) | III |
| Anatomical breast implant, single lumen, with B-Lite gel filler, round base, high profile and textured surface | SL Style 20636-xxxLW25 (xxx=70-670) | III |
| Anatomical breast implant, single lumen, with B-Lite gel filler, round base, low profile and textured surface | SL Style 20634-xxxLW25 (xxx=45-385) | III |



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| Product category | Product | Class |
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| Anatomical breast implant, single lumen, with B-Lite gel filler, round base, moderate profile and textured surface | SL Style 20635-xxxLW25 (xxx=60-525) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, extra high profile and fine-textured surface | SL Style 15677-xxxLW25 (xxx=110-855) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, high profile and fine-textured surface | SL Style 15676-xxxLW25 (xxx=95-855) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, low profile and fine-textured surface | SL Style 15674-xxxLW25 (xxx=60-495) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, moderate profile and fine-textured surface | SL Style 15675-xxxLW25 (xxx=75-670) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, extra high profile and Microthane [®] covered surface | SL Style 30677-xxxLW25 (xxx=110-855) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, extra high profile and textured surface | SL Style 20677-xxxLW25 (xxx=110-855) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, high profile and Microthane [®] covered surface | SL Style 30676-xxxLW25 (xxx=95-855) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, high profile and textured surface | SL Style 20676-xxxLW25 (xxx=95-855) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, low profile and Microthane [®] covered surface | SL Style 30674-xxxLW25 (xxx=60-495) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, low profile and textured surface | SL Style 20674-xxxLW25 (xxx=60-495) | III |



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| Product category | Product | Class |
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| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, moderate profile and Microthane [®] covered surface | SL Style 30675-xxxLW25 (xxx=75-670) | III |
| Anatomical breast implant, tall base, single lumen, with B-Lite gel filler, moderate profile and textured surface | SL Style 20675-xxxLW25 (xxx=75-670) | III |
| Round breast implant, double lumen, with B-Lite gel filler, extra high profile and smooth surface | DL Style 10627-xxxLW28 (xxx=260-920) | III |
| Round breast implant, double lumen, with B-Lite gel filler, extra high profile and textured surface | DL Style 20627-xxxLW28 (xxx=260-920) | III |
| Round breast implant, single lumen, with B-Lite gel filler, extra high profile and fine-textured surface | SL Style 15627-xxxLW25 (xxx=95-920) | III |
| Round breast implant, single lumen, with B-Lite gel filler, extra high profile and Microthane [®] covered surface | SL Style 30627-xxxLW25 (xxx=95-920) | III |
| Round breast implant, single lumen, with B-Lite gel filler, extra high profile and smooth surface | SL Style 10627-xxxLW25 (xxx=95-920) | III |
| Round breast implant, single lumen, with B-Lite gel filler, extra high profile and textured surface | SL Style 20627-xxxLW25 (xxx=95-920) | III |
| Round breast implant, single lumen, with B-Lite gel filler, high profile and fine-textured surface | SL Style 15626-xxxLW25 (xxx=80-760) | III |
| Round breast implant, single lumen, with B-Lite gel filler, high profile and smooth surface | SL Style 10626-xxxLW25 (xxx=80-760) | III |
| Round breast implant, single lumen, with B-Lite gel filler, high profile and textured surface | SL Style 20626-xxxLW25 (xxx=80-760) | III |
| Round breast implant, single lumen, with B-Lite gel filler, high profile with Microthane [®] covered surface | SL Style 30626-xxxLW25 (xxx=80-760) | III |
| Round breast implant, single lumen, with B-Lite gel filler, low profile and fine-textured surface | SL Style 15624-xxxLW25 (xxx=50-440) | III |



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| Round breast implant, single lumen, with B-Lite gel filler, low profile and Microthane [®] covered surface | SL Style 30624-xxxLW25 (xxx=50-440) | III |
| Round breast implant, single lumen, with B-Lite gel filler, low profile and smooth surface | SL Style 10624-xxxLW25 (xxx=50-440) | III |
| Round breast implant, single lumen, with B-Lite gel filler, low profile and textured surface | SL Style 20624-xxxLW25 (xxx=50-440) | III |
| Round breast implant, single lumen, with B-Lite gel filler, moderate profile and fine-textured surface | SL Style 15625-xxxLW25 (xxx=65-600) | III |
| Round breast implant, single lumen, with B-Lite gel filler, moderate profile and smooth surface | SL Style 10625-xxxLW25 (xxx=65-600) | III |
| Round breast implant, single lumen, with B-Lite gel filler, moderate profile and textured surface | SL Style 20625-xxxLW25 (xxx=65-600) | III |
| Round breast implant, single lumen, with B-Lite gel filler, moderate profile with Microthane [®] covered surface | SL Style 30625-xxxLW25 (xxx=65-600) | III |



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