

DECLARATION OF CONFORMITY



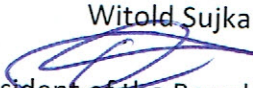
TRICOMED

Manufacturer: TRICOMED S.A.
Address of the manufacturer: 93-493 Łódź, Poland, 5/9 Świętojańska Street
Product: OPTOMESH® ULTRALIGHT
Surgical meshes for hernia repair
Types/models/versions: According to the appendix
Class of the product: II b
Expiry date: 5 years
Scope: The device stipulated in this declaration is compliant with essential requirements of Annex I of Directive 93/42/EEC and essential requirements of Health Minister Decree dated 17th February 2016 as for essential requirements and compliance evaluation procedure for medical devices.
Notified Body Fulfilment of requirements from Annex I of Directive 93/42/EEC has been confirmed by the Notified Body Polish Centre For Testing and Certification, 1434, dated 19th September 2019, certificate number 1434-MDD-461/2019 according to Annex II of the above quoted Directive.

TRICOMED S.A. holds certified Quality Management System, compliant with requirements of standard ISO 13485:2016 – certificate number: M – 76-a/1/2019.

We hereby declare with full responsibility that manufactured device to which this declaration refers is compliant with reference documents and standard referred to in the appendix to the technical documentation of the product.

Łódź, 23.07.2020 r.

Witold Sujka

The President of the Board

Annex: Product List OPTOMESH® ULTRALIGHT

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Annex to the Declaration of Conformity OPTOMESH® ULTRALIGHT

PRODUCT LIST OF OPTOMESH® ULTRALIGHT
Surgical meshes for hernia repair

Lp	Nazwa wyrobu	Rozmiar	Kod wyrobu
1.	OPTOMESH UltraLight L-Pore	50x60 mm	MA-271-OPUL-001
2.	OPTOMESH UltraLight L-Pore	20x80 mm	MA-271-OPUL-002
3.	OPTOMESH UltraLight L-Pore	20x100 mm	MA-271-OPUL-003
4.	OPTOMESH UltraLight L-Pore	60x90 mm	MA-271-OPUL-004
5.	OPTOMESH UltraLight L-Pore	50x120 mm	MA-271-OPUL-005
6.	OPTOMESH UltraLight L-Pore	60x110 mm	MA-271-OPUL-006
7.	OPTOMESH UltraLight L-Pore	80x130 mm	MA-271-OPUL-007
8.	OPTOMESH UltraLight L-Pore	75x150 mm	MA-271-OPUL-008
9.	OPTOMESH UltraLight L-Pore	90x130 mm	MA-271-OPUL-009
10.	OPTOMESH UltraLight L-Pore	80x150 mm	MA-271-OPUL-010
11.	OPTOMESH UltraLight L-Pore	100x150 mm	MA-271-OPUL-011
12.	OPTOMESH UltraLight L-Pore	50x300 mm	MA-271-OPUL-012
13.	OPTOMESH UltraLight L-Pore	60x300 mm	MA-271-OPUL-013
14.	OPTOMESH UltraLight L-Pore	120x170 mm	MA-271-OPUL-014
15.	OPTOMESH UltraLight L-Pore	150x150 mm	MA-271-OPUL-015
16.	OPTOMESH UltraLight L-Pore	125x200 mm	MA-271-OPUL-016
17.	OPTOMESH UltraLight L-Pore	150x250 mm	MA-271-OPUL-017
18.	OPTOMESH UltraLight L-Pore	150x300 mm	MA-271-OPUL-018
19.	OPTOMESH UltraLight L-Pore	200x300 mm	MA-271-OPUL-019
20.	OPTOMESH UltraLight L-Pore	250x250 mm	MA-271-OPUL-020
21.	OPTOMESH UltraLight L-Pore	300x300 mm	MA-271-OPUL-021
22.	OPTOMESH UltraLight L-Pore	350x300 mm	MA-271-OPUL-022
23.	OPTOMESH UltraLight L-Pore	300x450 mm	MA-271-OPUL-023
24.	OPTOMESH UltraLight M-Pore	50x60 mm	MA-271-OPUM-001
25.	OPTOMESH UltraLight M-Pore	20x80 mm	MA-271-OPUM-002
26.	OPTOMESH UltraLight M-Pore	20x100 mm	MA-271-OPUM-003
27.	OPTOMESH UltraLight M-Pore	60x90 mm	MA-271-OPUM-004
28.	OPTOMESH UltraLight M-Pore	50x120 mm	MA-271-OPUM-005
29.	OPTOMESH UltraLight M-Pore	60x110 mm	MA-271-OPUM-006
30.	OPTOMESH UltraLight M-Pore	80x130 mm	MA-271-OPUM-007
31.	OPTOMESH UltraLight M-Pore	75x150 mm	MA-271-OPUM-008
32.	OPTOMESH UltraLight M-Pore	90x130 mm	MA-271-OPUM-009
33.	OPTOMESH UltraLight M-Pore	80x150 mm	MA-271-OPUM-010
34.	OPTOMESH UltraLight M-Pore	100x150 mm	MA-271-OPUM-011
35.	OPTOMESH UltraLight M-Pore	50x300 mm	MA-271-OPUM-012
36.	OPTOMESH UltraLight M-Pore	60x300 mm	MA-271-OPUM-013
37.	OPTOMESH UltraLight M-Pore	120x170 mm	MA-271-OPUM-014
38.	OPTOMESH UltraLight M-Pore	150x150 mm	MA-271-OPUM-015


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39.	OPTOMESH UltraLight M-Pore	125x200 mm	MA-271-OPUM-016
40.	OPTOMESH UltraLight M-Pore	150x250 mm	MA-271-OPUM-017
41.	OPTOMESH UltraLight M-Pore	150x300 mm	MA-271-OPUM-018
42.	OPTOMESH UltraLight M-Pore	200x300 mm	MA-271-OPUM-019
43.	OPTOMESH UltraLight M-Pore	250x250 mm	MA-271-OPUM-020
44.	OPTOMESH UltraLight M-Pore	300x300 mm	MA-271-OPUM-021
45.	OPTOMESH UltraLight M-Pore	350x300 mm	MA-271-OPUM-022
46.	OPTOMESH UltraLight M-Pore	300x450 mm	MA-271-OPUM-023
47.	OPTOMESH UltraLight S-Pore	50x60 mm	MA-271-OPUS-001
48.	OPTOMESH UltraLight S-Pore	20x80 mm	MA-271-OPUS-002
49.	OPTOMESH UltraLight S-Pore	20x100 mm	MA-271-OPUS-003
50.	OPTOMESH UltraLight S-Pore	60x90 mm	MA-271-OPUS-004
51.	OPTOMESH UltraLight S-Pore	50x120 mm	MA-271-OPUS-005
52.	OPTOMESH UltraLight S-Pore	60x110 mm	MA-271-OPUS-006
53.	OPTOMESH UltraLight S-Pore	80x130 mm	MA-271-OPUS-007
54.	OPTOMESH UltraLight S-Pore	75x150 mm	MA-271-OPUS-008
55.	OPTOMESH UltraLight S-Pore	90x130 mm	MA-271-OPUS-009
56.	OPTOMESH UltraLight S-Pore	80x150 mm	MA-271-OPUS-010
57.	OPTOMESH UltraLight S-Pore	100x150 mm	MA-271-OPUS-011
58.	OPTOMESH UltraLight S-Pore	50x300 mm	MA-271-OPUS-012
59.	OPTOMESH UltraLight S-Pore	60x300 mm	MA-271-OPUS-013
60.	OPTOMESH UltraLight S-Pore	120x170 mm	MA-271-OPUS-014
61.	OPTOMESH UltraLight S-Pore	150x150 mm	MA-271-OPUS-015
62.	OPTOMESH UltraLight S-Pore	125x200 mm	MA-271-OPUS-016
63.	OPTOMESH UltraLight S-Pore	150x250 mm	MA-271-OPUS-017
64.	OPTOMESH UltraLight S-Pore	150x300 mm	MA-271-OPUS-018
65.	OPTOMESH UltraLight S-Pore	200x300 mm	MA-271-OPUS-019
66.	OPTOMESH UltraLight S-Pore	250x250 mm	MA-271-OPUS-020
67.	OPTOMESH UltraLight S-Pore	300x300 mm	MA-271-OPUS-021
68.	OPTOMESH UltraLight S-Pore	350x300 mm	MA-271-OPUS-022
69.	OPTOMESH UltraLight S-Pore	300x450 mm	MA-271-OPUS-023

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