

# DECLARATION OF CONFORMITY



**Manufacturer:** TRICOMED S.A.  
**Address of the manufacturer:** 93-493 Łódź, Poland, 5/9 Świętojańska Street  
**Product:** OPTOMESH®  
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 17<sup>th</sup> 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, certificate number 1434-MDD-382/2019 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®

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Annex to the Declaration of Conformity OPTOMESH®

**PRODUCT LIST OF  
OPTOMESH®  
Surgical meshes for hernia repair**

No	PRODUCT NAME	SIZE	INDEX
1.	OPTOMESH ThinLight	50x60 mm	MA-271-OPMT-001
2.	OPTOMESH MacroPore	50x60 mm	MA-271-OPMM-001
3.	OPTOMESH ThinLight	50x100 mm	MA-271-OPMT-002
4.	OPTOMESH MacroPore	50x100 mm	MA-271-OPMM-002
5.	OPTOMESH ThinLight	60x110 mm	MA-271-OPMT-003
6.	OPTOMESH MacroPore	60x110 mm	MA-271-OPMM-003
7.	OPTOMESH ThinLight	65x125 mm	MA-271-OPMT-004
8.	OPTOMESH MacroPore	65x125 mm	MA-271-OPMM-004
9.	OPTOMESH ThinLight	80x80 mm	MA-271-OPMT-005
10.	OPTOMESH MacroPore	80x80 mm	MA-271-OPMM-005
11.	OPTOMESH ThinLight	80x130 mm	MA-271-OPMT-006
12.	OPTOMESH MacroPore	80x130 mm	MA-271-OPMM-006
13.	OPTOMESH ThinLight	100x100 mm	MA-271-OPMT-021
14.	OPTOMESH MacroPore	100x100 mm	MA-271-OPMM-017
15.	OPTOMESH ThinLight	100x160 mm	MA-271-OPMT-007
16.	OPTOMESH MacroPore	100x160 mm	MA-271-OPMM-007
17.	OPTOMESH ThinLight	125x200 mm	MA-271-OPMT-008
18.	OPTOMESH MacroPore	125x200 mm	MA-271-OPMM-008
19.	OPTOMESH ThinLight	125x250 mm	MA-271-OPMT-009
20.	OPTOMESH MacroPore	125x250 mm	MA-271-OPMM-009
21.	OPTOMESH ThinLight	150x150 mm	MA-271-OPMT-010
22.	OPTOMESH MacroPore	150x150 mm	MA-271-OPMM-010
23.	OPTOMESH ThinLight	150x200 mm	MA-271-OPMT-011
24.	OPTOMESH MacroPore	150x200 mm	MA-271-OPMM-011
25.	OPTOMESH ThinLight	200x200 mm	MA-271-OPMT-022
26.	OPTOMESH MacroPore	200x200 mm	MA-271-OPMM-018
27.	OPTOMESH ThinLight	200x250 mm	MA-271-OPMT-012
28.	OPTOMESH MacroPore	200x250 mm	MA-271-OPMM-012
29.	OPTOMESH ThinLight	200x300 mm	MA-271-OPMT-013
30.	OPTOMESH MacroPore	200x300 mm	MA-271-OPMM-013

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31.	OPTOMESH ThinLight	220x350 mm	MA-271-OPMT-014
32.	OPTOMESH MacroPore	220x350 mm	MA-271-OPMM-014
33.	OPTOMESH ThinLight	260x360 mm	MA-271-OPMT-015
34.	OPTOMESH MacroPore	260x360 mm	MA-271-OPMM-015
35.	OPTOMESH ThinLight	300x300 mm	MA-271-OPMT-016
36.	OPTOMESH MacroPore	300x300 mm	MA-271-OPMM-016
37.	OPTOMESH ThinLight T-LI	60x140 mm	MA-271-OPMT-017
38.	OPTOMESH ThinLight T-LIK	60x140 mm	MA-271-OPMT-018
39.	OPTOMESH ThinLight T-LI	45x100 mm	MA-271-OPMT-019
40.	OPTOMESH ThinLight T-LIK	45x100 mm	MA-271-OPMT-020
41.	OPTOMESH MacroPore	50x60 mm	MA-271-OPMM-101
42.	OPTOMESH MacroPore	50x100 mm	MA-271-OPMM-102
43.	OPTOMESH MacroPore	60x110 mm	MA-271-OPMM-103
44.	OPTOMESH MacroPore	65x125 mm	MA-271-OPMM-104
45.	OPTOMESH MacroPore	80x80 mm	MA-271-OPMM-105
46.	OPTOMESH MacroPore	80x130 mm	MA-271-OPMM-106
47.	OPTOMESH MacroPore	100x160 mm	MA-271-OPMM-107
48.	OPTOMESH MacroPore	125x200 mm	MA-271-OPMM-108
49.	OPTOMESH MacroPore	125x250 mm	MA-271-OPMM-109
50.	OPTOMESH MacroPore	150x150 mm	MA-271-OPMM-110
51.	OPTOMESH MacroPore	150x200 mm	MA-271-OPMM-111
52.	OPTOMESH MacroPore	200x250 mm	MA-271-OPMM-112
53.	OPTOMESH MacroPore	200x300 mm	MA-271-OPMM-113
54.	OPTOMESH MacroPore	220x350 mm	MA-271-OPMM-114
55.	OPTOMESH MacroPore	260x360 mm	MA-271-OPMM-115
56.	OPTOMESH MacroPore	300x300 mm	MA-271-OPMM-116

Łódź, 23.07.2020 r.

Witold Sujka

The President of the Board