

DECLARATION OF CONFORMITY



TRICOMED

Manufacturer: TRICOMED S.A.
Address of the manufacturer: 93-493 Łódź, Poland, 5/9 Świętojańska Street
Product: OPTOMESH® SUPERULTRALIGHT
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 02.10.2020, certificate number 1434-MDD-362/2020 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, 29.10.2020 r.

Witold Sujka


The President of the Board

Annex: Product List OPTOMESH® SUPERULTRALIGHT

DECLARATION OF CONFORMITY



TRICOMED

Annex to the Declaration of Conformity OPTOMESH® SUPERULTRALIGHT

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

NO	Name of product	Size	Index
1.	OPTOMESH SuperUltraLight	50x60 mm	MA-271-OPSL-001
2.	OPTOMESH SuperUltraLight	50x100 mm	MA-271-OPSL-002
3.	OPTOMESH SuperUltraLight	60x110 mm	MA-271-OPSL-003
4.	OPTOMESH SuperUltraLight	65x125 mm	MA-271-OPSL-004
5.	OPTOMESH SuperUltraLight	80x80 mm	MA-271-OPSL-005
6.	OPTOMESH SuperUltraLight	80x130 mm	MA-271-OPSL-006
7.	OPTOMESH SuperUltraLight	100x100 mm	MA-271-OPSL-007
8.	OPTOMESH SuperUltraLight	100x160 mm	MA-271-OPSL-008
9.	OPTOMESH SuperUltraLight	125x200 mm	MA-271-OPSL-009
10.	OPTOMESH SuperUltraLight	150x200 mm	MA-271-OPSL-010
11.	OPTOMESH SuperUltraLight	150x150 mm	MA-271-OPSL-011
12.	OPTOMESH SuperUltraLight	200x200 mm	MA-271-OPSL-012

Łódź, 29.10.2020 r.

Witold Sujka


The President of the Board