

DECLARATION OF CONFORMITY



Manufacturer:	TRICOMED S.A.
Address of the manufacturer:	ul. Świętojańska 5/9, 93-493 Łódź, Poland
Registration number in the EUDAMED database:	PL-MF-000002483
Product name:	Optomesh® STOMA Surgical mesh for parastoma hernia repair
Basic UDI-DI code:	5900516EEDXXXVQ
Class of the product:	cl. IIb <i>Classification in accordance with Directive 93/42/EEC</i>
Intended use:	Optomesh® STOMA surgical meshes are intended for use during the surgical treatment of the causal or preventive occurrence of parastomal hernias. The most common indications for surgical treatment of hernias are: obstruction of intestinal passage, large hernia size, pain and discomfort while moving, chronic inflammatory changes around the stoma, entrapment episodes, and cosmetic considerations.
Expiry date:	5 year
Scope:	The product mentioned in this declaration complies with essential requirements of Annex I of Directive 93/42/EEC and essential requirements of Health Minister Decree dated 17 th 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 Center For Testing and Certification, 1434, dated 21 th May 2021, certificate number 1434-MDD-191/2021 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. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Łódź, 28.05.2021 r.

Witold Sujka

The President of the Board

Annex: Product List **Optomesh® STOMA**

DECLARATION OF CONFORMITY



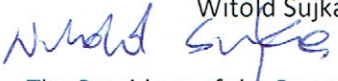
TRICOMED

Annex to the Declaration of Conformity **Optomesh® STOMA**

**PRODUCT LIST OF OPTOMESH® STOMA
SURGICAL MESH FOR PARASTOMA HERNIA REPAIR**

PRODUCT LIST OF OPTOMESH® STOMA			
NO	PRODUCT NAME	SIZE	INDEX
1	Optomesh® STOMA	195 x 195 mm	MA-271-OPST-001

Łódź, 28.05.2021 r.


Witold Sujka
The President of the Board