DECLARATION OF CONFORMITY

Manufacturer: TRICOMED S.A.

Address of the manufacturer: 93-493 Łódź, Poland, 5/9 Świętojańska Street

Product: MEDISORB P PLUS ADHESIVE – adhesive absorbent polyurethane dressing

Types/models/versions: Available in sizes Medisorb P Plus Adhesive: 10x10 cm, 15x15 cm, 20x20 cm

Class of the product: II b

Expiry date: 3 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.


Device stipulated in this declaration is compliant with the following harmonized standards:

PN-EN ISO 13485:2012
PN-EN ISO 15223-1:2012
PN-EN ISO 10993:1-2010
PN-EN ISO 14971:2012
PN-EN 1041+A1:2013


We hereby declare with full responsibility that manufactured device to which this declaration refers is compliant with reference documents.

Łódź, 16.11.2017 r.

Witold Sujka

The President of the Board