

Declaration of Conformity to the
Medical Device Directive 93/42 EEC as
amended 2007/47/EC For the following
devices;

Device Name: Disposable Surgical Gowns, Drapes and Drapes Pack

Classification & Rule: Class I / Rule 1 (acc. to Medical Device Directive -Annex 9)

GMDN Codes: 47782

Applicable Harmonized Standards:

EN ISO 13485:2016

EN ISO 15223-1:201

EN ISO 1041:2014

EN ISO 14971:2016

EN 13795 +A1

Device Groups:

- DISPOSABLE STERILE STANDARD SURGICAL GOWN M – REF. NO.: 0002
- DISPOSABLE STERILE STANDARD SURGICAL GOWN L – REF. NO.: 0003
- DISPOSABLE STERILE STANDARD SURGICAL GOWN XL – REF. NO.: 0004
- DISPOSABLE STERILE STANDARD SURGICAL GOWN XXL – REF. NO.: 0005
- DISPOSABLE STERILE REINFORCED SURGICAL GOWN M – REF. NO.: 0201
- DISPOSABLE STERILE REINFORCED SURGICAL GOWN L – REF. NO.: 0202
- DISPOSABLE STERILE REINFORCED SURGICAL GOWN XL – REF. NO.: 0203
- DISPOSABLE STERILE REINFORCED SURGICAL GOWN XXL – REF. NO.: 0204
- DISPOSABLE STERILE STANDARD SURGICAL GOWN M – REF. NO.: 0002
- DISPOSABLE STERILE STANDARD SURGICAL GOWN L – REF. NO.: 0003
- DISPOSABLE STERILE STANDARD SURGICAL GOWN XL – REF. NO.: 0004
- DISPOSABLE STERILE STANDARD SURGICAL GOWN XXL – REF. NO.: 0005

We declare that; this our non-sterile one is equal to sterile except than packaging & sterilization process. This products are comply with requirements of the MDD 93/42EEC as amended 2007/47 EC.



The devices also do not include animal or human tissue or derivatives, blood products, or products which would be considered to be medicinal products and all products are Latex-Free.

This is to certify that the above statement is true and relates to product manufactured from this date.

Signed *A. Mertgüneş* Date 20/11/2020

Being a duly authorised officer of the Company

Company

Nurel Medikal San.ve Tic.A.Ş.

Dosab Karanfil Sok.No:4/B

Bursa/Turkey