



EC DECLARATION OF CONFORMITY

BIOTEX MEDİKAL TEKSTİL İTHALAT İHRACAT SANAYİ VE TİCARET A.Ş.

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Product

Sterile Disposable Surgical Drapes, Gowns and Sets

GMDN

35778: Surgical gown
47783: Surgical set

Classification

Medical device Directive 93/42/EEC Annex IX Class IS in accordance with rule 1.(Sterile)

Conformity Assessment Path

Medical Device Directive 93/42/EEC quality assurance of the production Annex V

The products we offered above, together with all updates so far, the European Union's medical device Directive 93/42/EEC we declare that complies with the requirements of. All supporting documents to the manufacturer's resident resides at the address where it is stored.

Applicable Legislation

Medical Device Directive 93/42/EEC

Applied Standards

EN ISO 9001: 2015, EN ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008, EN 10993-1, EN 15223-1:2016, EN 13795:2013

Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.

Address

İTOSB 9. Cadde No:15 Tepeören Tuzla-İSTANBUL
TÜRKİYE

Notified Body Number

1984

Certificate Date, Certificate Number

05.03.2020-1984-MDD-17-549

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With the authority of the General Manager

Ertan Demir

Signature

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