DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q1N 23 21 43342 00

Holder of Certificate: **NİNOVA NÖROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SAN. VE TİC. LTD. ŞTİ.**
KONAK MAHALLESİ ÜNİVERSİTE BULVARI 127/1
ŞAHİNBEY - GAZİANTEP / TÜRKİYE

Facility(ies): NİNOVA NÖROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SAN. TİC. LTD. ŞTİ.
KONAK MAHALLESİ ÜNİVERSİTE BULVARI 127/1
ŞAHİNBEY - GAZİANTEP / TÜRKİYE

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: Production and Distribution of Surgical Drapes, Gown, Mask, Caps, Surgical Supporting Product, Irrigation pouch, Surgical Packs and Assembly of Procedure Kits

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 38766310

Valid from: 2020-07-05
Valid until: 2025-06-05

Date, 2020-07-05

I. Preiß
Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

UNIVERSALCERT.COM

UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate No: MDD-299

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Commission directive 2007/47/EEC amending Medical Devices Directive dated 05 September 2007,

the products manufactured by

NİNOVA NOROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SANAYİ VE TİCARET LİMİTED ŞİRKETİ

at the following address

Konak Mahallesi Üniversite Bulvarı No:127/1 Şahinbey GAZIANTEP / TURKEY

EN 13795-1:2019 Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns

Brand Name: NİNOVA
Model: MİLANO
(Standard Performance)are tested according to the following initial type tests by the manufacturer

For the assessment of conformity, the following documents were also reviewed:
Laboratory test results for Microbial Penetration (wet/dry), Bioburden, Bursting and Tensile Strengths (wet/dry)

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the surgical gowns manufactured and designed for use to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; performance level and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 30/10/2020 and valid until 29/10/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

ISTANBUL –30/10/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

EU DECLARATION OF CONFORMITY

MANUFACTURER

NİNOVA NOROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Konak Mahallesi Üniversite Bulvarı No:127/1 Şahinbey GAZIANTEP / TURKEY

PRODUCT DESCRIPTION

Brand Name: NİNOVA
Model: MİLANO

Surgical Gowns with standard performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as Medical Device (Class I)

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- European Regulation (EU) 2017/745 and 93/42/EEC Medical Devices Directive establishing technical requirements for medical devices, in effective wording
- Technical standard EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
- Other relevant harmonized legislation and standards
- For the assessment of conformity, the following documents were also applied to:
- Results of laboratory tests for Microbial Penetration - Wet and Microbial Cleanliness, Bioburden by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.
- Results of laboratory tests for Bursting and Tensile Strengths (wet/dry) by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.

MARKING, LABELLING

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the surgical gown is supplied. The information supplied with the product considering EN ISO 15223-1:2016 and EN 1041:2008+A1:2013.

MEASURES TO ENSURE CONFORMITY

The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

General Manager
30/10/2020

CE

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFIKÁ

Üretici Manufacturer: NİNOVA NÖROTEKNOLOJİ ARAŞTIRMA GELİŞTİRME SAN.VE TİC.LTD.ŞTİ.
Adres /Address: KONAK MAH. ÜNİVERSİTE BLV. 127 1 ŞAHİNBEY/ GAZİANTEP/ TÜRKİYE
Telefon / Phone: +90 342 336 36 20
Email : info@ninova.io

ÜRÜN İSMİ VE TİPLERİ / PRODUCT NAME AND TYPES

KORUYUCU ÖNLÜK / PROTECTIVE GOWN -CERRAHİ ÖNLÜK (TEK KULLANIMLIK) / SURGICAL GOWN/DISPOSABLE) HASTA ÖNLÜĞÜ / PATIENT GOWN - ZİYARETÇİ ÖNLÜĞÜ / VISITOR APRON -BOX ONLOGO/BOX APRON - AMELİYAT ÖNLÜĞÜ / SURGICAL GOWN- DOKTOR ÖNLÜĞÜ/DOCTOR GOWN CERRAHİ ÖNLÜK / SURGICAL GOWN

BEYAN/STATEMENT

Burada, AB tarafından sınıflandırılan Üretici,Dağıtıcı ve Temsilci olarak kendi sorumluluğumuzun altında, yukarıda ismi ve modeli geçen ürünlerin, 93/42/EEC Tıbbi Cihaz Direktifi ve yönetmeliklerine ve EK-1 Temel Gereklere uygun olarak gerektiğini beyan ederiz.

Here, we declare that the products listed above are manufactured under our own responsibility as a Manufacturer,Distributor / Representative by the EU, in accordance with the 93/42/EEC Medical Device Directive and regulations.

ÜRÜNÜN MARKASI / PRODUCT BRAND

NİNOVA

DİREKTİF VE YÖNETMELİKLER / DIRECTIVES AND REGULATIONS

93/42/EEC Tibbi Cihaz Direktifi /9342/EEC Medical Device Directive

HARMONİZE STANDARTLAR / HARMONIZED STANDARDS

93/42/EEC- Tıbbi Cihaz Yönetmeliği SINIF I (Steril Olmayan) Medical Devices Regulation / Class I (Non Sterile)
TS EN 13795-1 Cerrahi Giysiler Ve Örtüler - Gereklilikler Ve Deney Yöntemleri - Bolüm 1: Cerrahi Örtüler Ve Önlükler Surgical Clothing And Drapes - Requirement And Test Methods - Part 1: Surgical Drapes And Gowns
TS EN ISO 13485 Tıbbi Cihazlar - Kalite Yönetim Sistemleri - Düzenleyici Amaçlar için Gereklilikler Medical Devices - Quality Management Systems - Requirements For Regulatory Purposes
TS EN ISO 15223-1 Tıbbi Cihazlar - Tıbbi Cihaz Etiketlerinde. Etiketlemede ve Sunulacak Bilgide Kullanlacak Semboller - Bölüm 1: Genel Gerekler / Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling And Information To Be Supplied - Part 1:General Requirements
TS EN 1041+A1 Tıbbi Cihaz İmalatçıları Tarafından Sağlanan Bilgiler / Information Supplied By The Manufacturer Of Medical

Sertifika No / Certificate No: 2020.CE-2908
Sertifika Tarihi /Certificate Date: 22.05.2020
Sertifika Bitiş Tarihi /Certificate Expiration Date: 22.05.2021

Accredited System Certification Approval