

Surgical Gown

PRODUCT CODE

HND-IG-100-1



EU Personal Protective Equipment (PPE) Regulation (EU) 2016/425, Category I



FDA Class 1 Registered and Approved



Technical Specifications and Features

- Made from non-woven polyethylene-coated polypropylene
- Outer layer liquid penetration resistant in critical areas (full front and arms)
- Minimum average material density: 70gsm
- Isolation gown with long sleeves and a waist tie that binds at the back or front
- Length (measured at front from middle of neckline to bottom): 110 - 150 cm
- Width or circumference (measured at waist): minimum of 130 cm
- Sleeves finished with double layer cuff, cotton or synthetic, stretchy interlocked jersey, length: 4 - 8 cm
- Non-sterile
- Single use, disposable
- Universal size
- Fluid resistant

Measurements

Packaging
10 pcs. / bag

Weight
5.2 kg

Volume
0.037m³

SYMBOL OF TRUST
SINCE **1869**



PRODUCT CODES AND FDA APPROVED NAMES

OEA	Non-Surgical Isolation Gown
FXO	Suit, Surgical
LYU	Accessory, Surgical Apparel
QKR	Face Mask (except N95 respirator) for general public/healthcare personnel per IIE guidance
FME	Gown, Examination
MSH	Respirator, Surgical

FDA LISTING INC.



CERTIFICATE OF FDA REGISTRATION 2020

This is to certify that
H. NIZAM DIN & SONS (PRIVATE) LTD
D-64 S.I.T.E. Karachi, Sindh,
75730, Pakistan

is registered and listed the following device codes with the U.S. Food and Drug Administration pursuant to U.S. Code of Federal Regulations CFR Title 21, Part 807. This registration is being verified as valid on the signature date by FDA Listing Inc.

Establishment Owner /Operator Number: **10073161**
FDA Product Classification Code(s): **OEA, FXO, LYU, QKR, FME, MSH**
Official FDA U.S. Agent: **FDA Listing Inc. New York, USA**

This certificate confirms that the above-mentioned medical device establishment registration and device listings are verified as valid on the signature date and will remain effective till the end of year noted above. This certificate has only been issued for the confirmation of such registration and does not constitute as the FDA product approval. U.S. Food and Drug Administration does not issue any certificate of registration following medical device establishment registration and device listings. FDA Listing.com Inc. referred as FDA Listing Inc. is privately held regulatory assistance company with headquarters in New York, USA and has no affiliation with or endorsement by United States Food and Drug Administration.

FDA Listing Inc.

New York, USA
info@fdalisting.com www.fdalisting.com



FDA Listing Inc.

Certificate Issue date: 8th of May 2020

Signature: *M. Aminpour*

CERTIFICATE OF ASSESSMENT – EC

This is to certify, that the hereunder described items of Personal Protective Equipment have proving their conformity to the Safety and Health requirements of the Regulation (EU) 2016/425.

Product: **NON-WOVEN DISPOSABLE ISOLATION GOWN
PROTECTION COVERALL
WOVEN FACE MASKS**

Classification: **Category I
(accordingly, to the Manufacturer's declaration)**

Manufacturer: **H. NIZAM DIN & SONS (PVT) LTD.**

Address: **D-64, S.I.T.E.
Karachi - 75730, Pakistan.**

The manufacturer's technical documentation and the above mentioned product(s) has been assessed and shown to satisfy the relevant provisions of the above Regulation for the Simple Design, category I, Art. 8.3, Module A products through:

Technical standard:

EN 14126:2003 and EN ISO 13688:2013

With drawn up an EU declaration of conformity you are therefore licensed to CE mark the product(s) listed above in accordance with Article 17 of the regulation.

This certificate shall not be reproduced except in full and remain property of CNC Services to whom must be returned on request. The holder must inform CNC Services, of any substantial changes occurred in the product or process in order to examine whether this certificate remains valid.



For CNC Services



Project Engineer

Klass Dikken

Date of Issue: 20th April, 2020

Date of Expiry: 19th April, 2021

Certificate Number: **CNC/EEC/4753/20**

This certificate is valid until the date specified, valid only if embossed with CNC conformity and compliance stamp