



CERTIFICATE

We hereby declare that the technical file of product complied with the requirement of
Directive Medical Device 93/42/EEC

Applicants

Name : DHWANIT ENTERPRISE

Address : PLOT NO. 4, NAKSHTRA INDUSTRIAL HUB, NR. AMBA HOTEL, AHMEDABAD-INDOR
HIGHWAY, CHANDIAL-382433, GUJARAT, INDIA

Products : MEDICAL AND SURGICAL DRAPES, GLOVES & MASK, SURGICAL DRESSING,
SURGICAL GOWN, HOSPITAL UNIFORM, SURGICAL DISPOSABLES, SURGICAL
INSTRUMENTS AND EQUIPMENTS, SURGICAL IMPLANTS

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the Directive (2014/35/EU) on Low Voltage

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.

1. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
2. The certificate validity is conditioned by positive results or surveillance audits.
3. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
4. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above-mentioned product. It does not imply an assessment of the whole production.

Certificate number : CE-3226

Initial Registration Date : 29-03-2023

1st Surveillance Date : 28-03-2024

2nd Surveillance Date : 28-03-2025

Certificate Expiry Date : 28-03-2026

To verify certificate, visit at :

<http://theiaaf.uk>

**This certificate is validity till / on the surveillance audit date, if any case
Surveillance audit will not conduct the certificate will be expired or Suspended**

Issued by BQS Certification Services

Authorized Signatory





Annexure-1

DHWANIT ENTERPRISE

Certificate No. : - CE-3226

01	Knee O Drape	02	Hip U Drape	03	Shoulder Drape
04	Spinal Drape	05	Gynec Drape	06	Caesarean Drape
07	Surgeon Gown	08	Patient Dress	09	Laparoscopy Drape
10	Urology Drape	11	Craniotomy Drape	12	Angiography Drape
13	CABG Kit	14	General Surgery Drape	15	TKR Kit
16	THR Kit	17	Helmet Hood	18	Arthroscopy Drape
19	URS Drape	20	HIV Kit (Premium)	21	Delivery Kit
22	Major Drape	23	Universal drape kit	24	Utility drape
25	Bilateral Drape	26	CABG Adult Patient Drape Kit	27	C-section drape kit
28	Ent kit	29	Upper Extremity pack(kit)	30	Surgical Gown
31	Patient Gown	32	Reinforced Gown	33	Orthopedic Drape Kit(pack)
34	Disposable Laparotomy kit	35	Obstetric Clothing set	36	Ophthalmological Drape kit
37	Dilation and Craniotomy kit	38	Arthroscopic surgery kit(pack)	39	Water Soluble Bag
40	Cystoscopy drape kit	41	Neurosurgery drape kit	42	TURP Drape, PCNL Drape
43	Cathlab drape (kit)	44	Endoscopic Drape kit	45	MTP Drape kit
46	Dead Body Cover	47	Plain Sheet	48	SMS Sheet
49	Bed Sheet	50	Disposable Aprons	51	Poly Aprons
52	C-Arm Cover	53	Ophthalmic Drape	54	Ophthalmic Blades
55	Cannula, Eye Pad	56	Disposable Surgical Products	57	Instruments or Implant
58	PPE Kit	59	Non-Woven Surgical Products	60	Gauze Swab
61	Ortho Roll Cast Padding	62	Grey Bandage	63	Elastic Adhesive Bandage

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Authorized Signatory





Annexure-2

DHWANIT ENTERPRISE

Certificate No. : - CE-3226

64	IV Set Event	65	BT Set	66	P.M.O. Line (150 cm to 200cm)
67	Facial Vein Set	68	Foley Catheter	69	ET Tube
70	Oxygen Mask (Adult/Child)	71	Nebulizer Mask	72	Nasal Cannula
73	3-Ball Spirometer	74	HME Filter	75	Measure Volume Set
76	Urine Bag	77	High Concentration Mask	78	Multiple Vertin Mask
79	IV Cannula	80	Yankaur Suction	81	Surgical Mop
82	Crepe Bandage	83	Abdominal Pad	84	Adhesive Bandage

Issued by BQS Certification Services

Authorized Signatory



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