

# CERTIFICATE

We hereby declare that the technical file of product complied with the requirement of directives Medical Devices Directive 2007/47/EC (MDD)

## Applicants

Name : **MEDICO SATTVA HEATHCARE**

Regs. Address : NEAR FCI GODOWN, 0, KRISHNA COLONY, PALWAL, HARYANA-121102, INIDA

Factory : B4/4, SPAN INDUSTRIAL COMPLEX SECOND FLOOR, PHASE-1, F ROAD, OPP.  
KOTAK MAHINDRA, GIDC VATVA, AHMEDABAD-382445, GUJARTA, INDIA

Product : Design and Development, Manufacturer, Exporter/Supplier of Medical Disposable and Surgical Products, Rehabilitation & Walking Products for aids, orthotics, Prosthetic, Orthopedic Implant/ Disposables, Surgical Paper Tape/ Microporous Tape, Elastic Adhesive Bandage, Gamjee Rolls, Surgical Dressings, Surgical Drapes, Cotton Wool, Surgical Sutures, Lab Consumables, Hospital Equipments & Furniture

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 directives Medical Directive Directive 2007/47/EC (MDD)

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 : BQS24MSH119

Initial Registration Date : 27-03-2024

1<sup>st</sup> Surveillance Date : 20-02-2025

2<sup>nd</sup> Surveillance Date : 20-02-2026

Certificate Expiry Date : 20-03-2027

To verify certificate, visit at :

<http://bqsiaaf.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



# CERTIFICATE

## ANNEXURE-1

### MEDICO SATTVA HEALTHCARE

Certificate number : IQS24MSH119

S. NO.	PRODUCT NAME
01	STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT, MICRO DRIP INFUSION SET, FOR SINGLE USE
02	STERILE DISPOSABLE BLOOD ADMINISTRATION / TRANSFUSION SET WITH/WITHOUT AIR VENT, FOR SINGLE USE
03	STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT, FOR SINGLE USE ONLY
04	DISPOSABLE STERILE DIAL FLOW REGULATOR FOR SINGLE USE ONLY
05	STERILE TRACHEOBRONCHIAL MUCUS EXTRACTOR CATHETER FOR SINGLE USE ONLY
06	STERILE SCALP VEIN SET FOR SINGLE USE ONLY
07	STERILE RYLE'S / NASOGASTRIC / GASTRO DUODENAL / LEVIN'S, SALEM SUMP TUBE, KEHR'S T TUBE, INFANT FEEDING TUBE FOR SINGLE USE ONLY
08	STERILE UMBILICAL CORD CLAMP FOR SINGLE USE ONLY
09	STERILE FOLEY BALLOON CATHETER FOR SINGLE USE ONLY
10	STERILE HIGH PRESSURE MONITORING LINE FOR SINGLE USE ONLY
11	STERILE EXTENSION LINE WITH / WITHOUT THREE WAY STOP COCK FOR SINGLE USE ONLY
12	STERILE DISPOSABLE THREE WAY STOP COCK AS ACCESSORY TO PERFUSION SET FOR SINGLE USE ONLY
13	STERILE YANKAUR SUCTION SET FOR SINGLE USE ONLY
14	STERILE DISPOSABLE SINGLE USE ENDOTRACHEAL & RE INFORCE ENDOTRACHEAL TUBE WITH & WITHOUT CUFF FOR SINGLE USE ONLY
15	STERILE CLOSED WOUND SUCTION CATHETER FOR SINGLE USE ONLY
16	STERILE ABDOMINAL DRAINAGE CATHETER FOR SINGLE USE ONLY

Issued by IQS Certification Services



Authorized Signatory

# CERTIFICATE

## ANNEXURE-1

### MEDICO SATTVA HEATHCARE

Certificate number : DQS24MSH119

S. NO.	PRODUCT NAME
17	STERILE INTERCOSTAL DRAINAGE CATHETER FOR SINGLE USE ONLY
18	STERILE URINE COLLECTING BAG FOR SINGLE USE ONLY
19	OXYGEN MASK, HIGH CONCENTRATION OXYGEN MASK ALL TYPES & SIZES
20	STERILE NEBULIZER MASK FOR SINGLE ONLY
21	STERILE TWIN BORE NASAL OXYGEN CATHETER FOR SINGLE USE ONLY
22	STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY
23	STERILE CHEST DRAINAGE CATHETER / THORACIC DRAINAGE CATHETER WITH OR WITHOUT TROCAR FOR SINGLE USE ONLY
24	STERILE NELATON CATHETER FOR SINGLE USE ONLY
25	STERILE GUEDEL AIRWAY FOR SINGLE USE ONLY
26	STERILE MALE EXTERNAL CATHETER FOR SINGLE USE ONLY
27	STERILE CORRUGATED DRAINAGE SHEET FOR SINGLE USE ONLY
28	STERILE DISPOSABLE URINE CONTAINER FOR SINGLE USE ONLY
29	STERILE TUR SET FOR SINGLE USE ONLY
30	INCENTIVE SPIROMETER
31	STERILE BVF/HME DISPOSABLE BACTERIAL/VIRAL FILTER SINGLE USE ONLY
32	STERILE CATHETER MOUNT FOR BREATHING CIRCUIT FOR SINGLE USE ONLY
33	STERILE VEN LATOR CIRCUIT, IV CANNULA / CATHETER, SPINAL NEEDLE, DISPOSABLE SYRINGES, INSULIN SYRINGE FOR SINGLE USE ONLY
34	STERILE BAIN CIRCUIT FOR SINGLE USE ONLY
35	STERILE MVA KIT FOR SINGLE USE ONLY
36	STERILE INFANT MUCUS EXTRACTOR FOR SINGLE USE ONLY
37	KARMAN CANNULA FOR SINGLE USE ONLY
38	EXAMINATION GLOVES, SURGICAL GLOVES (POWDERED / POWDER FREE), NITRILE GLOVES, GYNE GLOVES

Issued by DQS Certification Services



Authorized Signatory