



Certification & Inspection

# Certificate of Compliance

## CE

Confirms that the medical products of class I according to the Medical Council Directive MDD 93/42/EEC of June 1993.

**Certificate No.: CE-10036**

### Manufacturer

**Name** : CRYSTAL HYGIENE  
**Address** : 50 BALIYAVAS, NR. GEETA HIGH SCHOOL, AMRAIWADI,  
AHMEDABAD - 380026, GUJARAT, INDIA.  
**Products** : SURGICAL DRESSING MATERIAL, SURGICAL  
DISPOSABLES, RESPIRATORY PRODUCTS & MEDICAL  
AND INDUSTRIAL SAFETY PRODUCTS

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 Directive Medical Council Directive MDD 93/42/EEC of June 1993.

### This certificate is issued under the following conditions:

1. 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.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
5. 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.

Validity of this certificate can be verified at [www.ukcertifications.co.uk/verify](http://www.ukcertifications.co.uk/verify)

Date of Certification	8th February 2019
1 <sup>st</sup> Surveillance Audit Due	7th February 2020
2 <sup>nd</sup> Surveillance Audit Due	7th February 2021
Certificate Expiry	7th February 2022

  
Authorised Signatory







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Appendix-I

Appendix to Certificate no. : CE-10036

Applicant : CRYSTAL HYGIENE



This certificate referred to above covers the following products like:

TYPE OF PRODUCTS	BRAND NAME	TYPE OF PRODUCTS	BRAND NAME
STERILE DRESSING PRODUCTS	CRYSTO-SWAB	RESPIRATORY CARE DISPOSABLES	YANKOUR SUCTION SET PLAIN TIP
	CRYSTO-MOP		LARYNGEAL MASK
	CRYSTO-EYE		VENTILATOR CIRCUIT - PLAIN ADULT/PAED.
	CRYSTO-PAD		VENTILATOR CIRCUIT - SINGLE WATER TRAP
	CRYSTO-RIBB		VENTILATOR CIRCUIT - DOUBLE WATER TRAP
	CRYSTO-FIX		BVF HME FILTER
NON-STERILE DRESSING PRODUCTS	CRYSTO-MOP		EXTENSION LINE
	CRYSTO-PLAST		PRESSURE MONITORING LINE
	CRYSTO-CREPE		DOUBLE SWIVEL MOUNT CATHETER WITH CAP
	CRYSTO-SOFT		AMBU BAG ADULT/PAED.
	CRYSTO-SWAB		BAIN CIRCUIT ADULT/PAED.
	CRYSTO-JEE		URINE COLLECTION BAG UROMETRY
RESPIRATORY CARE DISPOSABLES	GAUZE CLOTH SWAB		URINE COLLECTION BAG WITH HANGER
	NEBULIZER WITH MASK ADULT/PAEDIATRIC		I.D BELT ADULT/PAED.
	NASAL CANNULA ADULT/PAED./INFANT		LATEX EXAMINATION GLOVES (CRYSTO - CARE)
	OXYGEN MASK WITH TUBING ADULT/PAED.		FACE MASK (CRYSTO - SAFE)
	HIGH CONCENTRATION MASK ADULT/PAED.		SURGEON CAP (CRYSTO - CAP)
	NEBULIZER WITH T & MOUTH PIECE		BUFFEN CAP
	MULTIFLOW VENTURY MASK - ADULT	NON WOVEN GOWN	
	T OXYGENATOR WITH TUBE	PLASTIC GLOVES	
	GUIDAL AIRWAYS	PLAIN DRAPE	
	3 BALL SPIROMETER	CAMERA COVER	
NEBULIZER KIT WITH T PIECE	NITRILE EXAMINATION GLOVES (CRYSTO - CARE)		

*Daniel ..*

Authorised Signatory

