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# DET NORSKE VERITAS AS

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## CERTIFICATE OF CONFORMITY

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Application of Council Directive 93/42/EEC of 14 June 1993.

**Certificate No.: 2006-MUM-MDD-001**

This is to certify that the technical documentation for the product:

### **Medical Devices**

*Manufactured by:*

**Kiran Medical Systems**

Kiran Chambers, 303-A, Linking Road, Khar, Mumbai 400052, India

**complies with the requirements applicable to it**

The manufacturer's technical documentation, as required for Class I devices, has been reviewed and found to comply with the requirements in Annex VII, section 3.

Further identification and description of the products covered by this certificate are given in the Appendix.

*Original Certification Date*  
Mumbai, 2003-10-14

*Place and date*  
Mumbai, 2006-10-14

*This Certificate is valid until*  
2009-10-14

For Det Norske Veritas AS  
Mumbai Certification Services

*Compliance to the Standard in respect to the indicated scope is verified by the DNV approved registered Team Leader:*

Vijay Magan  
Lead Auditor

Prakash Tikare  
Manager, Mumbai Certification Services

*Any significant changes in the design or construction of the products, or amendments to the Directive or Standards referenced above may render this receipt invalid. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.*



## Certificate of Conformity

## APPENDIX

**Appendix to Certificate no.:** 2006-MUM-MDD-001  
**Manufacturer:** Kiran Medical Systems  
Kiran Chambers, 303-A, Linking Road  
Khar, Mumbai 400 052, India  
**Product group:** Medical Devices (X-Ray Accessories)

The Certificate referred to above covers the following devices:

1. X-ray Cassette
  - a. X-ray Cassette
  - b. X-ray Cassette with Identification Window
  - c. Deep Cassette (Grid Cassette)
  - d. Mammography Cassette
2. Intensifying Screen
  - a. Intensifying Screen
  - b. Dental Screen
  - c. Gradient Screen (Gradual Screen)
  - d. Mammography Screen
3. Protective Apparel
  - Thyroid Shield
  - Gonad Shield
  - Ovarian Shield
  - Dental Apron
  - Mini Apron
  - Cassette Cover
  - Cassette Half Cover

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Mumbai, 14 October 2006

Prakash Tikare

Manager, Mumbai Certification Services



# CERTIFICATE OF ASSESSMENT - EC

## DET NORSKE VERITAS

Application of Council Directive 89/686/EEC of 21 December 1989, as amended, issued as "Forskrift for konstruksjon, utforming og produksjon av personlig verneutstyr" by the Norwegian Directorate of Labour Inspection

**Certificate N°.: 2006-OSL-PPE-0044**

*This is to certify that the Quality System for the product group:*

### **Protective Clothing against X-rays**

*Manufactured by*

**Kiran Medical Systems**

**Kiran Chambers, 303-A, Linking Road, Khar, Mumbai 400 052, India**

**complies with the applicable requirements of the Directive.**

The quality system for these products has been assessed according to the procedure of conformity assessment described in Article 11 B. This Certificate is based on that the products have been EC Type Examined by other Notified Bodies according to Article 10.

Identification of the products covered by this certificate is given in the Appendix.

#### **Limitations:**

The manufacturer must inform Det Norske Veritas Certification AS of any plan for substantial changes to the quality system in order to examine whether this Certificate remains valid. Annual Periodical Audits will be held to verify the validity of this Certificate.

*Høvik, 08 February 2006*

for Det Norske Veritas Certification AS

*Line Gangeskar*

**Line Gangeskar**  
*Head of section, Product and Personnel  
Certification*

**CE**  
**0434**

*Valid until: 08 February 2011*

*Cecilie Gudesen Torp*

**Cecilie Gudesen Torp**  
*Project engineer*


**CERTIFICATE OF ASSESSMENT - EC APPENDIX**
**Appendix to Certificate No.: 2006-OSL-PPE-0044**
**Manufacturer: Kiran Medical Systems**
**Product group: Protective Clothing against X-rays**

The Certificate referred to above covers the following devices:

Nr.	Type/Name	EC Type Examination Certificate number	Date of Issuance	Notified Body
1.	Protective Gloves-ref.PG50	0073/864/162/11/05/0002	2005-11-22	IRSN
2.	Double Sided Apron-ref.DSA3535	0073/864/162/11/05/0003	2005-11-22	IRSN
3.	Double Sided Apron-ref.DSA2525	0073/864/162/11/05/0004	2005-11-22	IRSN
4.	Double Sided Apron-ref.DSA5050	0073/864/162/11/05/0005	2005-11-22	IRSN
5.	Double Sided Apron-ref.DSA5025	0073/864/162/12/05/0007	2005-12-13	IRSN
6.	Double Sided Apron-ref.DSA3525	0073/864/162/12/05/0008	2005-12-13	IRSN
7.	Double Sided Apron-ref.DSA5035	0073/864/162/12/05/0008	2005-12-13	IRSN
8.	Coat Apron-ref.CA25	0073/864/162/12/05/0009	2005-12-13	IRSN
9.	Coat Apron-ref.CA35	0073/864/162/12/05/0010	2005-12-13	IRSN
10.	Coat Apron-ref.CA50	0073/864/162/12/05/0011	2005-12-13	IRSN
11.	Skirt and Vest-ref. SKV3535	0073/864/162/12/05/0012	2005-12-13	IRSN
12.	Skirt and Vest-ref. SKV2525	0073/864/162/12/05/0013	2005-12-13	IRSN
13.	Skirt and Vest-ref. SKV5050	0073/864/162/12/05/0014	2005-12-13	IRSN
14.	Skirt and Vest-ref. SKV3525	0073/864/162/12/05/0015	2005-12-13	IRSN
15.	Skirt and Vest-ref. SKV5025	0073/864/162/12/05/0016	2005-12-13	IRSN
16.	Skirt and Vest-ref. SKV5035	0073/864/162/12/05/0017	2005-12-13	IRSN

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8 February 2006

*Cecilie Gudesen Torp*  
 Cecilie Gudesen Torp

**CE** 0434