

EC Declaration of Conformity

Manufacturer:

Kiran Medical Systems
A Division of Trivitron Healthcare Private Limited
D-117, 134, T.T.C Industrial Area, Shirvane
P.O. Nerul, Navi Mumbai 400 706, India

European Representative:

Dr. R. Droessler- N. Droessler GbR
Hoefferscheid 7
D-53819 Neunkirchen-Seelscheid, Germany

Declares that the new Personal Protective Equipment and Medical Device described hereafter:

Device Name: Radiation Protection Apparel

UMDNS:

14-491

Models: Double Sided Apron, Skirt & Vest, Coat Apron, Surgical Apron, Panoramic Apron, Protective Gloves (Duo), Protective Gloves (Mittens), Dental Apron, Thyroid Shield, Gonad Shield, Patient Apron (Gonad), Ovarian Shield

Product Description	LEADLITE	ULTRALITE	ZEROLEAD
	EC-Type Examination Cert : GB17/872880, GB17/872879	EC-Type Examination Cert : GB17/872882, GB17/872881	EC-Type Examination Cert : GB17/872878, GB17/872877
	Product Codes		
Double Sided Apron	DSA3535 LL, DSA2525 LL DSA5050 LL, DSA3525 LL DSA5025 LL, DSA5035 LL	DSA3535 UL, DSA2525 UL DSA5050 UL, DSA3525 UL DSA5025 UL, DSA5035 UL	DSA3535 ZL, DSA2525 ZL DSA5050 ZL, DSA3525 ZL DSA5025 ZL, DSA5035 ZL
Skirt & Vest	SKV3535 LL, SKV2525 LL SKV5050 LL, SKV3525 LL SKV5025 LL, SKV5035 LL	SKV3535 UL, SKV2525 UL SKV5050 UL, SKV3525 UL SKV5025 UL, SKV5035 UL	SKV3535 ZL, SKV2525 ZL SKV5050 ZL, SKV3525 ZL SKV5025 ZL, SKV5035 ZL
Coat Apron	CA25 LL, CA35 LL, CA50 LL	CA25 UL, CA35 UL, CA50 UL	CA25 ZL, CA35 ZL, CA50 ZL
Surgical Apron	SA25 LL, SA35 LL, SA50 LL	SA25 UL, SA35 UL, SA50 UL	SA25 ZL, SA35 ZL, SA50 ZL
Panoramic Apron	PN25 LL, PN35 LL, PN50 LL	PN25 UL, PN35 UL, PN50 UL	PN25 ZL, PN35 ZL, PN50 ZL
Protective Gloves	PG50 LL	PG50 UL	PG50 ZL
Protective Gloves (Mittens)	PGM25 LL, PGM35 LL, PGM50 LL	PGM25 UL, PGM35 UL, PGM50 UL	PGM25 ZL, PGM35 ZL, PGM50 ZL
Dental Apron	DA35 LL, DA50 LL	DA35 UL, DA50 UL	DA35 ZL, DA50 ZL
Thyroid Shield	TS 35 LL, TS 50 LL	TS 35 UL, TS 50 UL	TS 35 ZL, TS 50 ZL
Gonad Shield	GS50 LL	GS50 UL	GS50 ZL
Gonad Shield	GS100 LL	GS100 UL	GS100 ZL
Patient Apron (Gonad)	PA50 LL	PA50 UL	PA50 ZL

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D-117, TTC Industrial Area, Village Shirvane, P.O. Nerul, Dist. Thane, Navi Mumbai 400 706, India
Ph: +91 22 27630942 | Fax: +91 22 27671790 | Web: www.kiranxray.com

Regd. Office: Trivitron Healthcare Private Limited

Trivitron Sapthagiri Bhawan, No.15 IV Street, Abhiramapuram, Chennai 600 018, Tamil Nadu, India
Ph: +91 - 44 - 2498 5050 (6 lines) | Fax: +91 - 44 - 2498 5757 | Web: www.trivitron.com | CIN: U85110TN1998PTC040515

Patient Apron (Gonad)	PA100 LL	PA100 UL	PA100 ZL
Ovarian Shield	OS100 LL	OS100 UL	OS100 ZL
Head Shield	HS 25 LL, HS35 LL, HS 50 LL HS 100 LL	HS 25 UL, HS35 UL, HS 50 UL HS 100 UL	HS 25 ZL, HS35 ZL, HS 50 ZL HS 100 ZL

is in conformity with the provisions of **Regulation EU 2016/425** and, where such is the case, with the national standard transposing harmonized standard No **EN 61331-3:2014, EN 61331-1:2014**

is identical to PPE which is the subject of **EC-Type Examination Certificates** Nos. GB17/872880, GB17/872882, GB17/872878, GB17/872879, GB17/872881, GB17/872877 issued by SGS United Kingdom, 202B Worley Parkway, Western-Super-Mare, BS 22, 6WA, **Notified Body Number – 0120.**

is subject to the procedure set out in **Module D of the Directive Regulation EU 2016/ 425** under the supervision of the notified body SGS United Kingdom, 202B Worley Parkway, Western-Super-Mare, BS 22, 6WA, **Notified Body Number – 0120.**

Certificate of **CE marking IN09/78094** is valid until 23rd July, 2021

is in conformity with the provisions of **Council Directives 93/42/EC (Class – I)** and, where such is the case, with the national standard transposing harmonized standard No **EN 61331-3:2014, EN 61331-1:2014**

is subject to the **conformity assessment procedure set out in VII of the Directive 93/42/EEC**

A Quality Management System based on

ISO 13485: 2003 (Certificate no.IN10/81311 valid from 23 February 2017 to 31 March 2019)

has been implemented towards production & quality assurance

Place, Date of issue: Navi Mumbai, India Sep 21, 2018

Sanjay Terse

General Manager – Quality Assurance & Regulatory Affairs

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