



## Compliance Report

**Applicant:** Xinjiang Ke Lan Shuang Yi Medical Technology Stock Co., Ltd.

**Address:** No. 285, Donghuan Road, Tianshan District, Urumqi City, Xinjiang Province, P.R.China.

**Product:** Positioning and Fixation Baseplate, Positioning and Fixation Cushion, Thermoplastic Fixation Mask for Radiotherapy, Thermoplastic Orthosis and Low Temperature Thermoplastic Material

**Type:** See annex for details

**Product Classification:** Class I

**The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).**

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

**No. 02728**

**Initial Issue Date: 03 Jul 2017**

*Tony Chen*

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General Manager (Signature)





## Annex to Report (No. 02728 )

Xinjiang Ke Lan Shuang Yi Medical Technology Stock Co., Ltd.

Product Name	Type
Positioning and Fixation Baseplate	KL/-T-2, KL/-T-2-A, KL/-T-1, KL/-T-1-A, KL/-T-1Z, KL/-T-1Z-A, KL/-J-4A, KL/-J-4A-A, KL/-J-1A, KL/-J-1A-A, KL/-J-3A, KL/-F-6A, KL/-F-6A-A, KL/-F-5, KL/-F-5-A, KL-DF135, KL-DF196, KL-DF136, KL/TJ-1, KL-DF138, KL-DF139, KL-DF140, KL/DB-F, KL/DB-FS, KL-DF110, KL-DF111, KL-S, KL-L, KL-DLS, KL-DF126, KL-DF133, KL-DF148, KL-DF108, KL-DF109, KL-DF112, KL/DB-CT1
Positioning and Fixation Cushion	KL-180x80, KL-150x170, KL-100x150, KL-100x70, KL-50x60
Thermoplastic Fixation Mask for Radiotherapy	RXXXB, RXXXW
Thermoplastic Orthosis	JXXXL, JXXXM, JXXXS
Low Temperature Thermoplastic Material	GXXXW, GXXXB, GXXXR, GXXXS

This annex is only valid if attached to the report mentioned above.