Fiscal Year 2019

CERTIFICATION OF REGISTRATION

Certificate Holder:

HEBEI KANG SHENG YUAN SPORTS GOODS CO., LTD.
No.6, Fuyang West Road, Jizhou District,
Hengshui, Hebei, 053200, CHINA

Has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through

Owner/Operator Number: 10026755
Device Listing#:

Listing No.	Code	Device Name
[illegible]	[illegible]	[illegible]

FDA

Hwatest Compliance Services Co., Ltd.
6F, Weiyang Bldg., No.36, Fucheng Rd., Longhua,
Xiliang, Street, Baoan, Shenzhen China
Hwatest@hwatest.com www.hwatest.com

Tom
Executive Director
Issued: Oct.25, 2018
Cert. No.2018122501
Expiration Date: Dec.31.2019

CERTIFICATE OF CONFORMITY

Reference No. HTT1712280R01

Applicant : Hebei Kang Sheng Yuan Sports Goods Co., Ltd.
Address : No. 6, Fuyang West Road, Jizhou District, Hengshui, Hebei, China (Mainland)

Manufacturer : Same as applicant
Address : Same as applicant

Product : Sports Safety
Brand Name : Kangshengyuan
Model(s) No. : Wrist brace, Wrist brace, Knee brace, Ankle brace, Hand brace, Shoulder brace, Maternity belt, Postpartum belt, Waist brace, Elbow brace, Posture brace, Sell-self heat-insensitive bags, Leg and foot shapewear

CONFORMITY DETAILS

EU Directive	Applicable Standards	Test Report No.
Medical Devices (93/42/EEC)	EN ISO 14223-1:2016 EN 1041:2008+A1:2013 EN ISO 14971:2012 EN ISO 14983-1:2009/A1:2013 EN ISO 14983-6:2009 EN ISO 11993-10:2013	HTT1712280R-M01

We confirm that the Technical Documentation for the above mentioned Product complies with the applicable requirements of the Directive 93/42/EEC, as amended. 2007/47/EC). Referring to the intended use, this has conformed with successful results the review of the Manufacturer's Technical Documentation of the certified product according to above mentioned Directive and the applicable standards.

This Certificate is issued under the following conditions:

1) 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.
2) It applies only to the above mentioned Medical Devices.
3) The Manufacturer is obligated to assure conformity of all the Medical Devices of the respective model to the type reviewed by the mean of this Certificate.
4) Any significant changes in the Design or Process used to manufacture the Product, or revision to the Directives or standards referred above may require additional work by us.

CE

HCS
Authorized Signature
Date of Issue: (dd/mm/yyyy)

After fulfilling the relevant EU Legislation Requirements, the Manufacturer shall affix to each Medical Device, CE Marking according to the above Directive.

Hwatest Compliance Services Co., Ltd.
www.hwatest.com hwatest@hwatest.com

HAP

检测报告

报告编号 [illegible] 第 1 页 共 1 页

委托单位 [illegible]

样品名称 [illegible]

检测结果

检测日期 2019.03.28

检测结论 [illegible]

备注

HAP

检测报告

报告编号 [illegible] 第 2 页 共 3 页

检测结果 [illegible]

序号	检测项目		单位	检测方法	实测值	单项结论
1	外观		/	[illegible]	[illegible]	符合
2	pH值		无单位	[illegible]	6.5	符合
3	可萃取重金属含量(以Pb计)		mg/kg	[illegible]	ND	符合
4	偶氮染料	总量	mg/kg	[illegible]	ND	符合
		分析			ND	符合
		致癌芳香胺			ND	符合
5	偶氮染料	总量	mg/kg	[illegible]	ND	符合
		分析			ND	符合
		致癌芳香胺			ND	符合
6	偶氮染料	总量	mg/kg	[illegible]	ND	符合
		分析			ND	符合
		致癌芳香胺			ND	符合
7	偶氮染料	分析	mg/kg	[illegible]	ND	符合
		致癌芳香胺			ND	符合
8	邻苯二甲酸酯		mg/kg	[illegible]	ND	符合
9	甲醛含量(干重)		mg/kg	[illegible]	ND	/
10	阻燃剂*		/	[illegible]	[illegible]	符合

备注：

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检测报告

报告编号 [illegible] 第 3 页 共 3 页

1. 检测标准

依据 GB 32611-2016 进行检测。

序号	检测项目	标准要求	判定
1	标签要求的检测项目	符合 GB 32611-2016 表 1 的要求	符合
2	产品说明	符合 GB 32611-2016 表 1 的要求	符合
3	产品主体检测项目	符合 GB 32611-2016 表 1 的要求	符合
4	产品包装检测项目	符合 GB 32611-2016 表 1 的要求	符合
5	随附文件	符合 GB 32611-2016 表 1 的要求	符合
6	执行的产品标准	符合 GB 32611-2016 表 1 的要求	符合
7	宣传用语	符合 GB 32611-2016 表 1 的要求	符合
8	宣传材料禁用内容要求	符合 GB 32611-2016 表 1 的要求	符合
9	警示语标识	符合 GB 32611-2016 表 1 的要求	符合
10	其他要求	符合 GB 32611-2016 表 1 的要求	符合
	结论	符合	

备注：N.A.为不适用或未要求

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检测报告

报告编号 [illegible] 第 4 页 共 4 页

2. 可萃取铅及可萃取镉检测结果（单位：mg/kg）

检测方法：依据 GB/T 17592.2011、ICP-OES 进行检测。

检测项目	方法 No.	MDL	结果	判定
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

备注：