

TRBS-02 Face Shield

Item Name	Item No.	PICTURE	SIZE	Length	Width	Height	Package
Face Shield	TRBS-02		One Size	32cm	22cm,	3cm,	300 Pcs /CTN, 11.3KGS/CTN, 71.9*56.1*36.9 CM Weight: 30g/pc



FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the FDA Establishment Registration and Device Listing with the US Food & Drug Administration for the Fiscal Year 2020 of

TIANJIN TAIRUIBOSI MEDICAL APPLIANCE CO., LTD.
No.29 Wangqinzhuan Jingbao Industry district, Beichen district Tianjin,
TIANJIN, 300400, CHINA

The facility registration and device listing information:

Owner/Operator Number: 10061898		
Device Listing No.	Product Code	Product Name(s)
D363424	IQF	Head Cervical Thoracic Orthosis
D363425	IQK	Cervical Collar
D363426	ILH	Stroke Splint,Boxer Splint Hand Splint,Finger Splint; Adjustable Thoracolumbar Orthosis, Glove,Wrist brace Forearm Support
D363427	IQE	Waist Brace,Lumbar Orthosis, Rib Belt,Correction Belt,Clavicle Strap
D363428	IPT	Hyperextension Brace
D363429	MRI	Shoulder Orthosis ,Shoulder Brace
D363430	ILI	Arm Sling
D363431	IOY	Adjustable Elbow Brace
D363432	ION	Hand Exerciser
D363433	IQI	Adjustable Knee Orthosis ,Knee Brace, Knee Ankle Foot Orthosis,Children Hip Abduction Brace ,Children Hip Brace, Hip Knee Ankle Foot Orthosis; Hallux Valgus Brace,Orthosis Accessories,Hinges,Branch
D363434	KYS	Insole,Carbon Fiber Footplate
D363435	IPX	Prosthetic Suspension Belt
D363436	ITW	Ankle Brace,Carbon Fiber Ankle Foot Orthosis Foot Support; Foot Drop Traction Support
D363437	IPG	Fracture Walker Boot
D363438	KNP	Children Dennis Shoes, Diabetic Shoes, Decompression Shoes, Corrective Shoes
D363439	FSM	Prosthetic Components,Prosthetic Parts
D363440	IPR	Crutch
D388935	KPY	Face Shield
D388937	HOY	Goggles
D388938	QKR	Medical Mask; Face Mask
D388941	OEA	Isolation Gowns
D388942	EHY	Impression Foam Box

For and on behalf of
SUNGU Technical Service Inc.

Authorized Signature
Only used for the US Agent Signature

第一类医疗器械备案信息表

备案号：津械备20200081号

备案人名称	天津市泰瑞博思医疗器械有限公司
备案人组织机构代码	91120113300779343C
备案人注册地址	天津市北辰区北仓镇王秦庄村京宝工业区29号
生产地址	天津市北辰区北仓镇王秦庄村京宝工业区29号
产品名称	医用隔离面罩
型号/规格	TRBS01、TRBS02、TRBS03、TRBS05
产品描述	通常由高分子材料制成的防护罩、泡沫条和固定装置组成。非无菌提供，一次性使用。
预期用途	用于医疗机构中检查治疗时起防护作用，阻隔体液、血液飞溅或泼溅。
备注	
备案单位和日期	天津市药品监督管理局 医疗器械备案专用章 备案日期：2020年02月21日
变更情况	





