

Facility Registration and Device Listing information of Medical Device in FDA of FY2021

MDHC Life Technologies (Kunshan) Co., LTD.

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has completed the Facility Registration and Device Listing (as manufacturer) with the US FDA, through HUMISS INC. (U.S. Agent)

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Signature of Authorized Person

Janus St WV

(James St. WU)

The device listing in the annex of below page.



Fiscal Year 2021

Device Listing of Medical Device

Annex to cert No. HU-M-210918001

Listing Number	Premarket Submission	Product Code(s)	Device Name(s)	Activities	Models
D384391	510(k) exempt	KPY	Shield, protective, personnel	Manufacturer	MDHC Medical Face Shield
D384393	510(k) exempt	FXP	COVER, SHOE, OPERATING-ROOM	Manufacturer	MDHC Medical isolating shoe cover
D384386	510(k) exempt	OEA	Non-surgical isolation gown	Manufacturer	MDHC Isolation gown
D384385	510(k) exempt	MSH	Respirator, surgical	Manufacturer	MDHC Disposable Medical Mask
D384388	510(k) exempt	НОҮ	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydriatic eyewear)	Manufacturer	MDHC Medical Goggles
D451394	510(k) exempt	JRC	MICRO PIPETTE	Manufacturer	MDHC Pipette Tips
D451395	510(k) exempt	GJW	PIPETTE, PASTEUR	Manufacturer	MDHC Pasteur Pipettes
D451396	510(k) exempt	PTN	Reservoir, blood, cardiopulmonary bypass, exempt	Manufacturer	MDHC Reagent Reservoir
D451397	510(k) exempt	BTC	BAG, RESERVOIR	Manufacturer	MDHC Reservoir
D451399	510(k) exempt	KJA	Flask, tissue culture	Manufacturer	MDHC Culture Flasks
D451400	510(k) exempt	KIZ	DISH, TISSUE CULTURE	Manufacturer	MDHC Culture Dishes, MDHC Cell Culture Plates
D451402	510(k) exempt	GJG	PIPETTE, QUANTITATIVE, HEMATOLOGY	Manufacturer	MDHC Transfer pipette
D451403	510(k) exempt	KIY	CHAMBER, SLIDE CULTURE	Manufacturer	MDHC Cell Culture Slide
D451404	510(k) exempt	MXT	DEVICE, ACCESSORY, COOLING PLATE FOR TISSUE EMBEDDING STATION	Manufacturer	MDHC Cooling Box
D451405	510(k) exempt	KET	FILTERS, CELL COLLECTION, TISSUE PROCESSING	Manufacturer	MDHC Filtration Systems
D451406	510(k) exempt	MPQ	CONTAINER, SPECIMEN, URINE, DRUGS OF ABUSE, OVER THE COUNTER	Manufacturer	MDHC Disposable sampling tube
D451407	510(k) exempt	EFN	COTTON, ROLL	Manufacturer	MDHC Saliva Collection Kits
D451408	510(k) exempt	CCQ	NEBULIZER, MEDICINAL, NON- VENTILATORY (ATOMIZER)	Manufacturer	MDHC Disposable Intransal Atomization Device
D451409	510(k) exempt	EGN	SCISSORS, SURGICAL TISSUE, DENTAL	Manufacturer	MDHC Bandage scissors
D451410	510(k) exempt	HTD	FORCEPS	Manufacturer	MDHC Medical forceps
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End of the annex.