Jeringa desechable sin espacio muerto - 1ml - 25G 1" - Idóneas para la vacunación contra la COVID (caja 100 unidades)

Características técnicas:

- Cumplen la normativa Estándar (Standard) - ISO7886-1:2017
- Estructura principal: Barril, émbolo y pulsador, pistón
- Alcance de la aplicación: El producto se utiliza con aguja en inyección hipodérmica.
- Escala: 0.01ml
- Medidor de volumen de jeringa: 1ml 25G 1"
- Para un almacenamiento seguro la jeringa debe estar alejada de altas temperaturas y excesiva humedad (tiene que ser inferior al 80%).
- Mantenga las jeringas alejadas de productos corrosivos.

Utilización:

- Abra el envase con cuidado desde la carcasa y obtenga la jeringa.
- Junte la boquilla de conexión con la aguja.
- Retire la tapa protectora de la aguja.

Precauciones:

- No usar si el paquete está abierto o dañado.
- No usar después de la fecha de caducidad.
- Descartar después de su uso.
- Válido por cinco años.

Calle Sierra Filabres 1. Polígono Industrial La Olivilla.
CP:28946. Fuenlabrada (Madrid).
91 632 77 40
tienda@fisaude.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 044803 0031 Rev. 03

Manufacturer:

Jiangxi Hongda Medical Equipment Group Ltd.
39 South Shengli RD, Jinxian County
331700 Nanchang, Jiangxi Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Infusion sets for single use, Transfusion sets for single use, Syringes for single use, Sterile needles for single use, scalp vein sets for single use, Blood collection needles for single use, Sterile Single-use Dental Injection Needles,Sterile Autodisable Syringe for single use, Disposable Suction Catheter for use in Respiratory Tract, Disposable Stomach Catheter, Single-use Sterile rubber surgical gloves, Disposable sterile needle retractable safety syringe, IV Cannula for single use, Foley Catheter for single use, Endotracheal tube for single use, A.V. fistula needle sets for single use, Burette-type infusion sets for single use, Heparin cap for single use, Sterile insulin syringe for single use, Blood Tubing Set for Hemodialysis, Feeding tube for single use, Safety scalp vein sets for single use, High-pressure Angiographic syringes and Accessories for single use, Insulin pen needle for single use, Infusion pump for single use, Hollow Fiber Hemodialyzer, Single-use lightproof infusion set.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 044803 0031 Rev. 03

Report No.: BJ21089301

Valid from: 2021-03-16
Valid until: 2024-05-26

Date, 2021-03-16

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

JIANGXI HONGDA MEDICAL EQUIPMENT GROUP LTD.

NO.39 SOUTH SHENGLI ROAD, JINXIAN COUNTY, JIANGXI PROVINCE, CHINA

Testing Report of Syringe for single use

HD/JL-质-G008

Product Name	Syringe for single use		Specification	1ml 25Gx1
Mfg.Lot	Lot 20201228		Batch Q'TY	2000000pcs
Man date	20201228		Testing Q'TY	80pcs
Testing Standard	ISO7886-1:2017		Testing Date	2020-12-29~2021-1-6
Sterilization Lot	灭 20201228A31	灭 20201228A32	灭 20201228A33	灭 20201228B31
	灭 20201228B32			
Testing Result	Biological Performance: Qualified Physical Performance: Qualified Chemical Performance: Qualified			
Testing Conclusion	The product of this lot is conform to the requirements specified in ISO7886-1:2017 "Sterile hypodermic syringes for single use- part 1:syringes for manual use", being judged to be qualified			
Remarks				

Approved by: **Yang Qinghua**

Checked by: **Yang Qinghua**

Tested by: Zeng Xiaoli，Fu Mengling

Date: 2021-1-6

JIANGXI HONGDA MEDICAL EQUIPMENT GROUP LTD.

NO.39 SOUTH SHENGLI ROAD, JINXIAN COUNTY, JIANGXI PROVINCE, CHINA

Testing Report of Syringe for single use

Product Name	Syringe for single use	Specification	1ml 25Gx1
Mfg.Lot	Lot 20201228	Batch Q'TY	2000000pcs
Man date	20201228	Testing Q'TY	80pcs
Testing Standard	ISO7886-1:2017	Testing Date	2020-12-29~2021-1-6

Testing Item	Technical Requirements	Sampling Method	Testing Result	Item Judgement
Cleanliness 清洁度	When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300lx to 700lx the surface of the hypodermic syringe which comes in contact with injection fluids during normal use shall be free from particles and extraneous matter	13[2 3]	passed	Qualified
Limits for acidity or alkalinity 酸碱度限制	The PH value of an extract prepared of accorder to A shall be within one unit of pH of that the control fluid.	-	0.27	Qualified
Limits for extractable metals 可萃取金属限制	An extract shall contain not greater than a combined total of 5mg/l of lead, tin, zinc and iron, when corrected for the metals content of the control fluid.	-	3.5mg	Qualified
	The cadmium content of the extract shall be lower than 0.1mg/l, when corrected for the cadmium content of the control fluid.	-	0.06mg	Qualified
Lubricant 润滑剂	The lubricant shall not be visible under normal or corrected-to-normal vision. as droplets or particles.	13[2 3]	passed	Qualified
	The quantity of lubricant used should not exceed 0.25 mg /cm^2 of the internal surface area of the syringe barrel. The quantity of lubricant used should not exceed 0.6%(m/m) of the mass of the barrel.	13[2 3]	passed	Qualified
Tolerance on graduated capacity 刻度容量允差	1,Nominal capacity V＜5ml： If less than half nominal capacity ±(1.5% of V+2% of expelled volume); 2,Nominal capacity V≥ 5ml： If less than half nominal capacity ±(1.5% of V+1% of expelled volume);	20[1 2]	-0.002~0.011ml	Qualified
	1,Nominal capacity V＜5ml：If equal to or greater than half nominal capacity ±5% of expelled volume； 2,Nominal capacity V≥ 5ml： If equal to or greater than half nominal capacity ±4% of expelled volume	20[1 2]	0.08~1.6%	Qualified
Graduated scale 刻度尺	The scale shall be graduated at least at the intervals given in table 1,The unit of volume shall be marked on the barrel	13[2 3]	0.01ml	Qualified

Testing Report of Syringe for single use

	The graduation lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel. The graduation line shall be evenly spaced. The ends of all graduation lines similar length shall be vertical beneath each other. The lengths of the short graduation lines on each scale shall be approximately half the length of the long lines.		passed	Qualified
	The graduation lines shall be numbered at the volume increments given in table 1		0.1ml	Qualified
	The overall length of scale shall be as given in table 1.		56.71~56.93mm	Qualified
Barrel 外套	The length of the barrel shall be such that the syringe has a maximum usable capacity of at least 10% more than the nominal capacity.	13[2 3]	11.2~12.9%	Qualified
	The open end of the barrel shall be provided with finger grips that shall ensure that the syringe will not roll more than 180° when it is placed on a flat surface at an angle of 10 to the horizontal. The finger grips shall be free from flash and sharp edges. Finger grips should be of adequate size, shape and strength for the intended purpose and should enable the syringe to be held securely during use.		passed	Qualified
Piston/plunger assembly 活塞/芯杆组件	The plunger should not be easily withdrawed completely from the barrel.	13[2 3]	passed	Qualified
	8 mm for syringes of nominal capacity up to but excluding 2 ml; 9 mm for syringes of nominal capacity of 2ml up to but excluding 5 ml; 12.5 mm for syringes of nominal capacity of 5 ml and greater.		13.9~14.5mm	Qualified
	When the syringe is filled with water and held vertically with first one end and then the other end uppermost. The plunger shall not move by reason of its own mass.		passed	Qualified
	The fiducial line shall be in contact with the inner surface of the barrel.		passed	Qualified
Nozzle 锥头	The male conical fitting of the syringe nozzle shall be in accordance with ISO 594-1 or ISO 594-2;	13[2 3]	passed	Qualified
	The nozzle lumen shall have a diameter of not less than 1.2 mm.		2.0~2.02mm	Qualified
Dead Space 残留量	When tested in accordance with annex C, the volume of liquid contained in the barrel and the nozzle when the piston is fully inserted shall be as given in table 1.	13[2 3]	0.0147~0.0261 mm	Qualified

JIANGXI HONGDA MEDICAL EQUIPMENT GROUP LTD.
NO.39 SOUTH SHENGLI ROAD, JINXIAN COUNTY, JIANGXI PROVINCE, CHINA

Testing Report of Syringe for single use

Freedom from air and liquid leakage past piston 正压和负压	When tested in accordance with annex D, there shall be no leakage of water past the piston or seal. When tested in accordance with annex B, there shall be no leakage of air past. the piston or seal, and there shall be no fall in the manometer reading.	20[1 2]	passed	Qualified
Sliding Performance 滑动性能	Syringe shall have good sliding performance. The pull-push force shall conform to the provisions specified in ISO7886-1:1993	13[2 3]	passed	Qualified
Packaging 包装	Should meet the requirements	13[2 3]	passed	Qualified
Labeling 标签	The package labeling should be complete, the content should meet the requirements.	13[2 3]	passed	Qualified