

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 17 05 43199 023

Manufacturer:

Suzhou Hengxiang Import & Export

Co., Ltd. 18F., 1638 Xi Huan Road 215004 Suzhou PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)



Eiffestraße 80 20537 Hamburg GERMANY

Product Category(ies): Laparotomy Sponges, X-Ray Detectable Gauze Swabs, Surgical Gloves, Acupuncture Needles, Surgical Blades, Disposable Syringes, Infusion Sets, Blood Transfusion Sets, Scalp Vein Sets, Sterile Hypodermic Needle for Single Use, Syringe for Insulin, Auto-disable Syringe, Nasal Oxygen Cannula, Oxygen Mask, Endotracheal Tube, Wound Drainage Reservoir, Latex Foley Catheter, Humidifier Bottle, Series of Nebulizer with Mask, Extracorporeal Circulation Conduct of Blood Purification Apparatus, First Aid Kits, Digital Thermometers, Blood Pressure Monitors, Infrared Ear Thermometers, Infrared Forehead Thermometers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:

Valid from: Valid until: SH17116EXT01 2017-06-14 2022-06-13

1. Pumil



Date, 2017-06-13

Stefan Preiß

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

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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®



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Facility(ies):

Suzhou Hengxiang Import & Export Co., Ltd. 18F., 1638 Xi Huan Road, 215004 Suzhou, PEOPLE'S REPUBLIC OF CHINA

Suzhou Hengxiang Import & Export Co., Ltd. 11F., 888 Chenghu Road, 215168 Suzhou, PEOPLE'S REPUBLIC OF CHINA

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SERINGĂ STERILĂ CU AC	3-PART, 10 ML 21G X 1	6	China		Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017
SERINGĂ STERILĂ CU AC	3 - PART, 3 ML 23G X 1 1/4"	Þ	China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017
SERINGĂ STERILĂ CU AC	2 - PART, 10 ML 21G X 1 1/2"		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	02-03-2017
SERINGĂ STERILĂ CU AC	3 - PART, 2 ML 23G X 1 1/4"	.	China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017
SERINGĂ STERILĂ CU AC	2 - PART, 20 ML 21G X 1 1/2"		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017
SERINGĂ STERILĂ CU AC	3 - PART, 10 ML 22G X 1 1/2"	ę	China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017
SERINGĂ STERILĂ CU AC	3 - PART, 5 ML 22G X 1 1/2"	8	China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017
SERINGĂ STERILĂ CU AC	3 - PART, 50 ML 18G X 1 1/2"		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017
SERINGĂ STERILĂ CU AC	2 - PART, 5 ML 22G X 1 1/4"		China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017
SERINGĂ STERILĂ CU AC	3-PART, 20 ML 21G X 1 1/2	ą	China	SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	2102-60-50

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DM000002730	SERINGĂ STERILĂ CU AC		2-PART 1/2*	2-PART, 5 ML 226 X 1 1/2*	1	China	***	SUZHOU HENGKIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	2102-60-50		
DM000002794	SIERINGĂ STIERILĂ CU AC PENTRU INSULINĂ	[]	3 - PART INSULIN	3 - PART, JML 29G X 1/2", INSULIN U-100		China		SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017		
DM00000787	SERINGĂ STERILĂ CU AC		3-PART 1/4"	3-PART, 5 ML 226 X 1 1/4"	9	China		SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	2102-60-50		
DM000002778	SERINGĂ STERLĂ CU AC	U	2-PAK1 1/4"	2-PART, 2ML 236 X 1 1/4"		China		SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017		×
DM000022835	SERINGĂ STERILĂ CU AC	D	3-PART 1/2"	3-PART, 20 ML 205 X 1 1/2"	9	China		SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	I.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017		
DM000002777	SERINGĂ STERILĂ CU AC	U	2 - PART	2 - PART, 2 ML 23G X 1"		China		SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017		
DM000002784	SERUNGĂ STERILĂ CU AC	u	3 - PART	3 - PART, 2 ML 236 X 1"	0	China		SUZHOU HENGXIANG IMPORT & EXPORT CO., LTD.	Î.M. BECOR S.R.L.	A07.PS-01.Rg04-169	05-09-2017		
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