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中国国际贸易促进委员会



China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书 CERTIFICATE



231100B0/035846

号码 No.

兹证明：在所附符合性声明上的东洋松蒲乳胶(锦州)有限公司的印章属实。

THIS IS TO CERTIFY THAT: the seal of DONGYANG SONGPU LATEX (JINZHOU) CO.,LTD. on the annexed DECLARATION OF CONFORMITY is genuine.



China Council for the Promotion of International Trade



授权签字:

Authorized

Gao Lichao

Signature:

日期: 2023年06月05日

(Date: Jun. 05, 2023)

证明网址 Website for verifying the certificate: <http://www.rzccpit.com/validate.html>



CE Technical Documentation

東洋松蒲乳膠(錦州)有限公司



DONGYANG SONGPU LATEX(JINZHOU)CO.,LTD.

Doc ID: SP/CE-001

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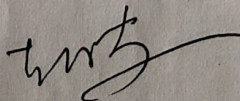
13 Declaration of Conformity

Doc ID: SP-WI-40-2018, C/0

	MANUFACTURER:	Dongyang Songpu Latex (Jinzhou) Co., Ltd. New and High-tech Development Zone, Jinzhou 121000, Liaoning Province P. R. China.
	MEDICAL DEVICE:	Condom (GMDN: 45138); Brand: CX, FREELY
	Specification:	52/55 ± 2 mm Smooth type, Float type, Thread type, and Float combined thread type
	CLASSIFICATION - ANNEX IX:	Class IIb, Rule 14
	CONFORMITY ASSESSMENT ROUTE:	MDD 93/42/EEC Annex II.3
<p>WE, THE MANUFACTURER, HEREBY DECLARE THAT THE STATED MEDICAL DEVICE MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. (WE, AS MANUFACTURER, ARE EXCLUSIVELY RESPONSIBILITY FOR THE DECLARATION OF CONFORMITY)</p>		
	APPLIED STANDARDS	EN ISO 13485: 2016, EN ISO 14971: 2019, IEC 62366-1: 2015, EN ISO 4074: 2015, EN ISO 10993-1: 2020, EN ISO 10993-5: 2020; EN ISO 10993-10: 2023, EN ISO 11737-1: 2018, EN ISO 11607-1: 2019, EN ISO 11607-2: 2019, ASTM F1980-16, ASTM D4169-16, EN ISO 15223-1: 2021, EN 1041: 2008. MEDDEV 2.7.1 Rev 4, MEDDEV 2.12_2 Rev 2, MEDDEV 2.12_1 Rev 8, MDD 93/42/EEC
	NOTIFIED BODY:	TUV SUD Product Service GmbH Ridlerstr 65, D-80339 Munchen, Germany
	IDENTIFICATION NUMBER	 0123
	(EC) CERTIFICATE(S):	G1 054496 0005 Rev. 01
	EXP. DATE:	2024-05-26
	EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse, 80, d-20537, Hamburg, Germany. Tel: +86 021-65951371, 0049-40-2513175 , Fax: +0049-40-255726;



START OF CE-MARKING: 2005-07

PLACE, DATE OF DECLARATION:	Jinzhou / 2023-05-24
SIGNATURE:	 2023.5.24
	NAME: MR. BO LU POSITION: MANAGEMENT REPRESENTATIVE



Rev.: C/2

Issued date: 2020-08-20



T. C. PEKİN BÜYÜKELÇİLİĞİ
Yukarıdaki imza ve mühürün Çin Halk Cumhuriyeti
Dışişleri Bakanlığı Konsolosluk Bölümüne
ait olduğu tasdik olunur.

Genel No.: 3074
Özel No.: 3204
Tarih: 14.06.2023



Ali Murat AKPINAR
İkinci Katip