

## DECLARACIÓN UE DE CONFORMIDAD

Guantes de vinilo sintético sin polvo color transparente Rfas. 910055690007 -  
910055690008

Nombre del fabricante o, en su caso, del importador:

RBTS Enterprise S.L.



El objeto de la declaración es conforme al documento expedido por el Fabricante Tangshan Lanhai Medical Suppliers Co. LTD número 02980 por el que Certifica que cumplen las directivas Europeas clasificando los Guantes de vinilo sin polvo color transparente relacionados corresponden a la categoría I y cumplen los requerimientos CE según la normativa Anexo I & VII del 93/42/EEC incluyendo la directiva 2007/47/EC

En conformidad con la declaración del fabricante Tangshan Lanhai Medical Suppliers Co. LTD se adjunta Compliance Report y certificado 00115Q26748R3M/1300 indicando el cumplimiento de la norma ISO9001:2008 GB/T19001-2008

En Las Palmas de Gran Canaria a, 08 de Mayo de 2020



RBTS



## Compliance Report

Applicant: TANGSHAN LANHAI MEDICAL SUPPLIES CO., LTD  
Address: South Side of Zhongda Street, East Side of Jinxiu Road, Chengxi Industrial Zone, Luannan County, Tangshan City, Hebei, P.R.China

Product: Disposable PVC Glove  
Type: S/M/L/XL

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02980

Initial Issue Date: 29 Oct 2018

A handwritten signature in blue ink that reads 'Tony Chen'.

General Manager (Signature)



# 质量管理体系认证证书

证书编号: 00115Q26848R3M/1300

兹证明

唐山鸿蕴塑料制品有限公司

组织机构代码: 77915665-7

中国河北省唐山市滦南县扒齿港镇绳各庄村南

建立的质量管理体系符合标准:

ISO9001:2008 GB/T19001-2008

通过认证范围如下:

一次性PVC手套的生产制造

首次发证日期: 2006年7月4日    本次发证日期: 2015年7月14日    有效期至: 2018年7月13日

在一个监督周期后, 本证书必须与CQC签发的监督审核合格通知书合并使用方可有效。查询证书有效状态请登录www.cqc.com.cn。  
本证书信息可在国家认证认可监督管理委员会官方网站(www.cnca.gov.cn)上查询



Signed by: Wang Kejiao



## 中国质量认证中心

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