

**ALERTA DE CONTROL DE MERCADO DE PRODUCTOS SANITARIOS
CERTIFICADO DE MARCADO CE FALSO**

Nº DE ALERTA: 2021-287	REFERENCIA PS/CV/RGA/5060
PRODUCTO Guantes quirúrgicos estériles de látex y nitrilo libres de polvo de la marca comercial "Superieur Gloves".	
FABRICANTE Nombre: Desconocido Dirección: Route 1, Long Thanh Industrial Zone Long Thanh District, Dong Nai Province, 76211, Vietnam.	
REPRESENTANTE AUTORIZADO Desconocido	
ASUNTO Detección en el mercado europeo de un certificado de marcado CE falso	
INFORMACIÓN ADICIONAL Datos del certificado CE falso: • Organismo Notificado y nº de identificación: TÜV SÜD Product Service GmbH (0123) • Número de certificado: G2 0493 Rev.03 • Fabricante: Nombre desconocido, Vietnam • Productos: Guantes quirúrgicos estériles de látex y nitrilo libres de polvo de la marca comercial "Superieur Gloves". • Fecha de emisión: 19 de febrero de 2020 • Fecha de caducidad: 28 de julio de 2024 Puede consultar información sobre productos sanitarios especialmente utilizados durante la COVID-19 que han sido detectados en el mercado y no cumplen la regulación en el link: https://www.aemps.gob.es/la-aemps/ultima-informacion-de-la-aemps-acerca-del-covid%e2%80%9119/informacion-sobre-productos-sanitarios-especialmente-utilizados-durante-la-covid-19-que-han-sido-detectados-en-el-mercado-y-no-cumplen-la-regulacion/	
DOCUMENTOS ADJUNTOS Certificado de marcado CE falso.	





Product Service

CE 2777 Certificate

Production ouality Assurance System

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

No. G2 0493

Rev. 03

Manufacturer:

Route 1, Long Thanh Industrial Zone
Long Thanh District, Dong Nai Province
76211, Vietnam

Trade Mark :

Superieur Gloves.

Product Category(ies):

Latex and Nitrile Surgical Powder free Glove, Sterile

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 I and II devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:

MYQM0319070Rev2-721358413

Valid from:

2020-02-19

Valid until:

2024-07-28

Date, 2020-02-19

C.D.H

Christoph Dicks
Head of Certification/Notified Body





Certificate

No. P2 075269 0011 Rev. 003

Holder of Certificate: **Route 1, Long thanh Industrial zone**
Long thanh District, Dong Nai Province
76211, Vietman.

Facility(ies): Route 1, Long Thanh Industrial Zone
Long Thanh District, Dong Nai Province
76211, Vietnam.

Report Certification : EN 388: 2 PROTECTIVE GLOVES AGAINST CHEMICAL RISKS
EN 455: 1 Medical Gloves for Single use, Requirements and testing
for freedom from holes.
EN 455: 2 Medical Gloves for Single use, Requirements and testing
for physical properties.

**EN
455**



Scope of Certificate:

1. Non-Sterile Natural Rubber Nitrile Gloves.
2. Non-Sterile Synthetic Rubber Latex Examination Glove
3. Sterile Natural Rubber Nitrile Surgical Glove
4. Sterile Synthetic Rubber Latex Surgical Glove

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TUV SUD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: MYQMH1218060-79359813

Valid from: 2019-05-05
Valid until: 2020-06-30

Date, 2019-05-05

Stefan Preiß