

**ALERTA DE CONTROL DE MERCADO DE PRODUCTOS SANITARIOS
CERTIFICADOS DE MARCADO CE FALSOS**

Nº DE ALERTA: 2024-060	REFERENCIA PS/VCG/NM/6502		
PRODUCTO <ul style="list-style-type: none">• Compresores de aire medicinal sin aceite.• Sistemas de succión dental.			
FABRICANTE Suzhou Junwei Medical Equipment Co., Ltd, Hall 91 No_116, Wutaishan Road Suzhou Italy Industrial Park Suzhou Science & Technology Town Suzhou National Hi-Tech District, Suzhou, China.			
ASUNTO Detección en el mercado europeo de dos certificados de marcado CE falsos			
INFORMACIÓN ADICIONAL Datos de los certificados CE falsos: <ul style="list-style-type: none">• Organismo Notificado y nº de identificación: TÜV SÜD Product Service GmbH (0123),• Fabricante: Suzhou Junwei Medical Equipment Co., Ltd			
Número de certificado falsificado	Productos /Modelos	Fecha de emisión	Fecha de caducidad
0123/ G2 1804 82113 008	Sistemas de succión dental	25-05-2023	24-05-2025
0123/Q8 082551 0003 Rev. 01	Compresores de aire medicinal sin aceite y sistemas de succión dental	25-04-2022	24-05-2025
El Organismo Notificado TÜV SÜD Product Service GmbH ha confirmado que no ha emitido dichos certificados para el fabricante Suzhou Junwei Medical Equipment Co, Ltd. Lo que se comunica a efectos de control de mercado.			
DOCUMENTOS ADJUNTOS <ul style="list-style-type: none">• Nota informativa de la AEMPS, referencia PS, 05/2024• Certificados de marcado CE falsos.			



Product Service

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 18 04 82113 008

Manufacturer: **Suzhou Junwei Medical
Equipment Co., Ltd.**

Hall 91, No.116, Wutaishan Road
Suzhou Italy Industrial Park
Suzhou Science & Technology Town
Suzhou National Hi-Tech District
215153 Suzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding
Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Dental Suction Systems**

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.: SH23665EXT01

Valid from: 2023-05-25

Valid until: 2025-05-24



Date, 2023-04-25

Stefan Preiß

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

Page 1 of 2



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No. G2 18 04 82113 008

Facility(ies):

Suzhou Junwei Medical Equipment Co., Ltd.
Hall 91, No.116, Wutaishan Road, Suzhou Italy Industrial
Park, Suzhou Science & Technology Town, Suzhou
National Hi-Tech District, 215153 Suzhou, PEOPLE'S
REPUBLIC OF CHINA