

N/REF: PS/RPS/663/2023

O F I C I O

Comunicación: RPS/663/2023
Nº AEMPS: 23-00924
Fecha: 16/03/2023
Asunto: **Anotación de la comunicación en el Registro de Responsables de la puesta en el mercado de Productos Sanitarios**

CMC Medical Devices & Drugs S.L
Horacio Lengo 18
29006 - Málaga
MÁLAGA
Andalucía

Con fecha **16/03/2023** ha sido **registrada** en la aplicación de Registro de Responsables de la puesta de mercado de Productos Sanitarios (RPS) de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) la comunicación presentada por **CMC Medical Devices & Drugs S.L.**, con la siguiente información:

1. Número de identificación asignado en el registro

RPS/663/2023

2. Responsable de la puesta en el mercado de los productos sanitarios

Empresa **CMC Medical Devices & Drugs S.L**
Horacio Lengo 18
29006 - Málaga (MÁLAGA)
Andalucía

En calidad de **Representante**

3. Legislación que declara cumplir:

PS - Reglamento (EU) 2017/745.

4. Página(s) adicional(es) de productos sanitarios incluidos en esta comunicación.

REGISTRO DE RESPONSABLES DE LA PUESTA EN EL MERCADO DE PRODUCTOS SANITARIOS
DEPARTAMENTO DE PRODUCTOS SANITARIOS

Nota.- Esta notificación no tiene el carácter de una autorización sanitaria de comercialización, ni entraña un juicio sobre la conformidad del producto con la legislación vigente. Únicamente avala el cumplimiento del Registro de Responsables según el artículo 24 del RD 1591/2009 por el que se regulan los Productos Sanitarios.

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 16/03/2023

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://localizador.aemps.es>

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ANEXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

Nombre comercial Tipo de producto	Fecha de introducción en el mercado Finalidad
<p>1 - Filling Instruments (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120FillingInstrumentRP) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held dental instrument specially designed to collect, transport and deposit amalgam in its plastic state into prepared cavities. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>2 - Dental Syringes (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120DentalSyringesXA) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held manual dental instrument consisting of a barrel (cylinder) with plunger/piston intended to be used for injecting an anaesthetic agent, subcutaneously or intramuscularly, from a prefilled, single-use cartridge through an attached sterile needle; a needle is not included. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>3 - Accessory (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120AccessoryXH) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A head-worn device consisting of a circular concave mirror (reflector) attached to a headband designed to reflect light to a site of examination/minor intervention (e.g., the nose, throat, or body surface) on a patient. The examiner wears the device on his/her head, places the reflector in front of one eye, and views the site through a small hole in the centre of the reflector. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>4 - Scissors (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120ScissorsRE) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held dental instrument designed to cut metal bands. It comprises two pivoted blades that are usually provided with a finger and thumb ring-handle and which cut with a shearing action (i.e., the blades cut as the sharpened edges pass one another as they are closed). It is typically made of high-grade stainless steel and has short, robust, blades that can cut through the thin metal strips (bands). This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

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<p>5 - Universal Saw (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120UniversalSawVK) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held manual device designed to cut through or trim the plaster of a cast. It is typically a one-piece device consisting of a handle attached to a short, curved, toothed blade made of high-grade stainless steel. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>6 - Forceps (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120ForcepsY2) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held manual dental instrument designed for grasping and holding a dental dressing during its application to a patient's oral cavity. It typically has a tweezers-like design with two conjoined blades with serrated tips at the working end. It is made of high-grade stainless steel and is available in various sizes. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>7 - Clamps (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120ClampsJS) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A surgical instrument designed to hold together surgical towels and/or drapes and/or other devices, e.g., cables/leads that need securing to the site of intervention, e.g., the towels/drapes surrounding or covering the patient/operating table. It is typically made of high-grade stainless steel and can have a variety sizes and designs, e.g., it can have two blades joined at their midpoint that have ring handles at the proximal end, or it may be a single alpha-shaped part joined at the proximal end, whilst the working end may be sharply-pointed, blunted, fenestrated or have various shaped gripping jaws. It is commonly known as a towel clamp, -forceps, or a -clip. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan



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<p>8 - Retractor (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120RetractorsLL) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A prefabricated oral device designed to protect the teeth, bones, and tissues of the mouth from damage due to impact/trauma typically during endoscopic diagnostic procedures, contact sports, and/or to prevent teeth grinding/clenching (bruxism). It is made of standard, preformed materials or items for adaptation to/direct insertion into the mouth; some types are referred to as nightguards or bite raising appliances. This is a reusable device.</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>9 - Articulators (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120ArticulatorsF7) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held manual dental instrument designed for grasping and holding articulation paper during its application to a patient's oral cavity. It typically has a tweezers-like design with two conjoined blades with serrated tips at the working end. It is made of high-grade stainless steel and is available in various sizes. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>10 - Ligature Tools (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120LigatureTools6X) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held dental instrument used to tuck and direct ligatures under the archwire or bracket wings or to push archwires or auxiliaries into position. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>11 - Pliers (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120PliersQR) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held manual dental instrument designed to hold small objects or to bend or to cut metal strips or wire used in orthodontic procedures. It is typically made of high-grade steel and consists of two arms/rods that form a handle proximally and extend distally through a pivot point to terminate with jaws available in various shapes depending on intended use. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan



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<p>12 - Band Pusher (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120BandPusherNU) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A band or strip of strong material (typically stainless steel or transparent polyester) or a short tube that is used to form a mould around a tooth for the insertion of restorative materials. The device is held snugly around the tooth by a matrix retainer or tensioned around the tooth using a dedicated mechanical tensioning device. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>13 - Explorers (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120ExplorersM6) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held manual dental instrument designed for tactile examination (i.e., exploration) in the oral cavity, on the tooth surface and/or gums, mainly to find indentations (e.g., pits, fissures) for the determination of early tooth decay on the crown of teeth. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>14 - Dental Files (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120DentalFiles2L) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held manual dental instrument with a small blade at an acute angle (e.g., 90 degrees) to its stem is intended to be used with a pulling action to remove gross amounts of supragingival calculus, and some subgingival calculus, in large wide-open pockets. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>15 - Grinding Tools (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120GrindingTools4Q) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A manually-operated, non-patient-contact device intended to be used to grind bone into a slurry or a powder for use as a bone matrix for bone regeneration or bone grafting. This is a reusable device.</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan



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<p>16 - Matrix Retainers (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120MatrixRetainersUB) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 The matrix retainer holds the matrix band in the correct position and is an aid for dental fillings. This is a reusable device.</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>17 - Holloware (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120HollowareFF) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A receptacle designed to hold wrapped and/or unwrapped medical/dental devices in a chemical washer/disinfector and/or sterilizer during the washing/disinfection and/or sterilization cycle(s). This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>18 - Crown Remover (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120CrownRemoverDM) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A non-electric, hand-held dental instrument intended to be used to remove a permanent or temporary cemented dental prosthesis restoration (e.g., crown, denture, bridge) from a tooth or implant abutment; it is not a thermal detacher. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>19 - Rubber Dam (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120RubberDam7F) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A dental device with a buccal and lingual wing, or flange, is used to anchor a rubber dam down to the cervical region of an exposed tooth. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan



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<p>20 - Spatula (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120SpatulasTS) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held manual dental device used to manipulate filling materials in the plastic state. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>21 - Diagnostic (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120DiagnosticsCS) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 The segment of a laryngoscope (i.e., rigid intubation type) intended to be inserted into the oral cavity to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anesthesia and/or ventilation. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>22 - Mallets (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120MalletsWC) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 Mallets are used in various dental procedures, mainly with chisels or wedges to split teeth or remove the bone. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>23 - Mouth Mirrors and Handles (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120MouthMirrorHandleHY) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A hand-held, dental instrument intended to be used by a dentist for intraoral inspection or inspection and retraction. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan



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<p>24 - Dental Examination Kit (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120DentalExaminatio5W) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A collection of various dental instruments and the necessary materials (e.g., aspiration cannula, forceps, mirror, probe, spatula, excavator) intended to be used to perform a dental examination. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan
<p>25 - Impression Tray (Non-sterile, non-active, non-measuring, reusable) (UDI-DI BÁSICO : ++G120ImpressionTrayWJ) PRODUCTOS SANITARIOS Clase I</p>	<p>16/03/2023 A horseshoe-shaped receptacle made of metal is designed to carry dental impression material to the mouth, to confine the material in opposition to the surfaces to be recorded (e.g., teeth and gums), and to control the impression material while it sets to form an impression. This is a reusable device</p>
Fabricante	Pais
Falcon Surgical Co. (Pvt) Ltd	PAKISTÁN / Pakistan



