MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

CERTIFICADO CE DE GARANTÍA DE CALIDAD DE LA PRODUCCIÓN
de acuerdo con el Anexo V de la Directiva 93/42/CEE

EC PRODUCTION QUALITY ASSURANCE CERTIFICATE
in accordance with Annex V of Directive 93/42/EEC

PRÓRROGA/*EXTENSION* — **Fecha inicial/** *Initial date*: **02-06-1998**
Fecha de última prórroga/ *Last extension date:* **20-05-2013**

Certificado nº/*Certificate no*	**Fecha de validez/*Date of validity***	**ON nº/*NB no***
98 06 0100 CP	**Desde/*From* 20-05-2018 Hasta/*To* 19-05-2023**	**0318**

A favor de /*In favour of:*

Fabricante/*Manufacturer*:
Nombre/*Name:* J. RIPOLL, S.L.
Dirección/*Address:* C/Rio Tiétar, 20 Pol. Ind. El Nogal 28110 Algete Madrid (ESPAÑA/ SPAIN)
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category***: Productos dentales**/ *Dental devices*
Grupo genérico/*Generic group***: Especificados en Anexos de este Certificado**/*Specified in Annexes to this Certificate.*
Tipo/*Type***: Especificados en Anexos de este Certificado**/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities:*

Nombre/*Name:* J. RIPOLL, S.L.
Dirección/*Address:* C/Rio Tiétar, 20 Pol. Ind. El Nogal 28110 Algete Madrid (ESPAÑA/SPAIN)

Este certificado debe ir acompañado por/*This certificate must be accompanied by*:

☐ Certificado de examen CE de tipo (anexo III)/*EC Type examination certificate (annex III)*
☑ Declaración CE de conformidad (anexo VII)/*EC declaration of conformity (annex VII)*

Este certificado es consecuencia de la auditoría del sistema de garantía de calidad de la producción y del examen de la documentación técnica contenida en el expediente nº 97 11 0064, y garantiza que los productos descritos cumplen los requisitos de la Directiva/*This certificate is issued on the production quality assurance system audit, and the examination of the technical documentation contained in dossier nº. 97 11 0064, and guarantees that the described products fulfil the requirements of the Directive.*

Madrid, 18 de mayo de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Belén Crespo Sánchez-Eznarriaga

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 18/05/2018
Localizador: RWF4688BED

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

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ORGANISMO NOTIFICADO 0318

Primero/*First* ☒
Complementario/*Complementary* ☐

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE DE GARANTÍA DE CALIDAD DE LA PRODUCCIÓN
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A favor de /*In favour of:*

Fabricante/*Manufacturer*:
Nombre/*Name:* J. RIPOLL, S.L.
Dirección/*Address:* C/Rio Tiétar, 20 Pol. Ind. El Nogal 28110 Algete Madrid (ESPAÑA/ SPAIN)
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem
Dirección/*Address:* Idem

Tipo de producto / *Device type*: **Productos dentales/***Dental devices* **(NANDO code: MD 0402)**
Clasificación/*Classification:* IIa

1. MATERIALES PARA PREPARACIÓN DE SUPERFICIES/ *PREPARATION MATERIALS OF SURFACES*

1.1. Gel ácido grabador dental de Ac. Fosfórico 37%/ *37% phosphoric acid, dental etching gel [GMDN code 36153]*

1.1.a) 1 jeringa 12 g verde/ *1 syringe 12 g green*

1.1.b) 1 jeringa 12 g azul/ *1 syringe 12 g blue*

1.1.c) 2 jeringas 3,5 g verde/ *2 syringes 3,5 g green*

1.1.d) 3 jeringas 3,5 g verde/ *3 syringes 3,5 g green*

1.1.e) 4 jeringas 3,5 g verde/ 4 syringes 3,5 g green

1.1.f) 3 jeringas 3,5 g azul/ *3 syringes 3,5 g blue*

1.1.g) 4 jeringas 1,2 ml azul/ *4 syringes 1,2 ml blue*

1.1.h) 1 jeringa 60 g azul + 2 jeringas azul 3,5 g/*1 syringe 60 g blue + 2 syringes 3,5 g blue*

1.1.i) 1 jeringa 60 g verde + 2 jeringas verde 3,5 g/ *1 syringe 60 g green + 2 syringes 3,5 g green*

1.1.j) 1 jeringa 47 g verde + 2 jeringas verde 3,5 g/ *1 syringe 47 g green + 2 syringes 3,5 g green*

1.1.k) 1 jeringa 36 g azul + 2 jeringas azul 1,2 ml/ *1 syrunge 36 g azul + 2 jeringas 1,2 ml blue*

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2. CEMENTOS DENTALES/ *DENTAL CEMENTS*

2.1. Cemento dental de óxido de Cinc (40 g) – Eugenol (20 ml)/ *Dental cements, Zinc oxide (40 g)-Eugenol (20 ml) [GMDN code 16182]*

3. PELICULAS PROTECTORAS (BARNIZ)/ *PROTECTIVE FILMS (VARNISH)*

3.1. Barniz de resina de Copal/*Copal resin varnish [GMDN CODE 35698]*

4. MATERIALES DE RELLENO ENDODÓNCICO (USO EN CANALES RADICULARES DENTALES)/ *ENDODONTIC FILLING MATERIALS (TO USE IN DENTAL RADICULAR CANALS) [GMDN CODE 35698]*

4.1. Q Crema (EDTA 15%)/ *Q EDTA Gel (EDTA Gel 15%)*

4.1.a) Q Crema (EDTA 15%) de 1,2 ml/ *Q EDTA Gel (EDTA Gel 15%), 1,2 ml*
4.1.b) Q Crema (EDTA 15%) de 3 ml/ *Q EDTA Gel (EDTA Gel 15%), 3 ml*
4.1.c) Q Crema (EDTA 15%) de 10 ml/ *Q EDTA Gel (EDTA Gel 15%), 10 ml*

4.2. Q Solución (Solución EDTA 17%)/ *Q Solution (EDTA Solution 17%)*

4.2.a) Q Solución (Solución EDTA 17%) de 30 ml / *Q Solution (EDTA Solution 17%), 30 ml*
4.2.b) Q Solución (Solución EDTA 17%) de 100 ml / *Q Solution (EDTA Solution 17%), 100 ml*

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 18 de mayo de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Belén Crespo Sánchez-Eznarriaga

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Date: 06/09/2024
Reference: JRI059_DEX03_20240906v1
NOTIFIED BODY CONFIRMATION LETTER

J. Ripoll, S.L.
C/ Rio Tiétar, 20. Pol. Ind. El Nogal
28110 Algete - Madrid
España

NOTIFIED BODY CONFIRMATION LETTER
REFERENCE: JRI059_DEX03_20240906v1

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, **THE CENTRO NACIONAL DE CERTIFICACIÓN DE PRODUCTOS SANITARIOS**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0318** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

J. Ripoll, S.L.
C/ Rio Tiétar, 20. Pol. Ind. El Nogal
28110 Algete - Madrid
España
ES-MF-000001256

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices.
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors).
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments).

On behalf of the Notified Body,

Madrid, 06 de septiembre de 2024
Jefa del Centro Nacional de Certificación de Productos Sanitarios

Fdo. Gloria Hernández Hernández

CORREO ELECTRÓNICO
secretariaCNCps@certificaps.gob.es

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CEMENTO DENTAL DE ÓXIDO DE ZINC-EUGENOL 843604224ZOETHN	Class IIa	N/A	CE Certificate nº 98 06 0100 CP Epigraph 2.1 Notified Body 0318
ÁCIDO GRABADOR 843604224GELACGRAB36	Class IIa	N/A	CE Certificate nº 98 06 0100 CP Epigraph 1.1 Notified Body 0318
BARNIZ DE RESINA DE COPAL 843604224COPAL9C	Class IIa	N/A	CE Certificate nº 98 06 0100 CP Epigraph 3.1 Notified Body 0318
QCREMA (EDTA 15%) 843604224ACONDCANALRAD8L	Class IIa	N/A	CE Certificate nº 98 06 0100 CP Epigraph 4.1 Notified Body 0318
QSOLUCIÓN (EDTA 17%) 843604224ACONDCANALRAD8L	Class IIa	N/A	CE Certificate nº 98 06 0100 CP Epigraph 4.2 Notified Body 0318
ALATO 843604224ALATO7M	Class IIa	N/A	CE Certificate nº 2019 05 0886 CP Epigraph 1.1 Notified Body 0318

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/09/06	JRI059_DEX03_20240906v1	Initial issue