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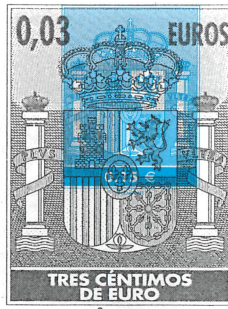
06/2019



**JOSEP PEÑARROJA FA**  
ADVOCATE AND SOLICITOR  
COMMISSIONER FOR OATHS  
OFFICIAL TRANSLATOR  
GRAN VIA 594 SA 2ª  
08007 BARCELONA SPAIN



CLASE 8ª



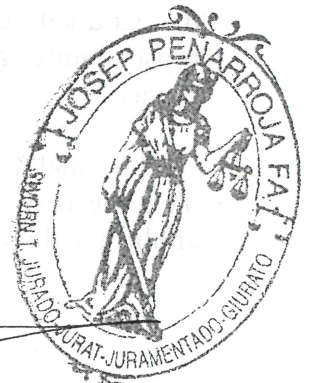
*Traducción Jurada* *Official translation*

*Josep Peñarroja Fa*  
*Intérprete Jurado de Inglés*  
*Official Translator of English*

*Certifica que la que antecede es traducción*  
*fiel y completa al inglés de un documento*  
*redactado en español.*

*Do hereby certify that the attached translation*  
*is a true and accurate rendering into English*  
*of a document in Spanish.*

*Barcelona,* - 3 MAR 2020





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CLASE 8.ª

# Traducción Jurada

[Coat of arms of Spain]

**MINISTRY OF HEALTH**

[Logo]

Spanish Medicines and Medical Devices Agency

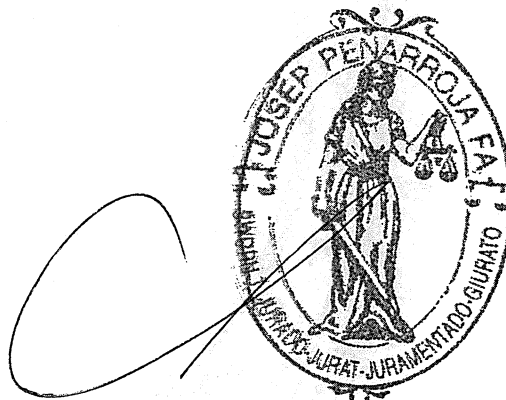
## NOTIFICATION

OUR REF.: PS/DP/MFD  
DATE: 19 February 2020  
RE: Information to the recipient

RECIPIENT: **BIOSYSTEMS, S.A.**  
**C/ COSTA BRAVA, N.º 30**  
**08030 BARCELONA (SPAIN)**

With regard to the products listed below, produced by your company, considering that they are subject to external quality assessment procedures:

- PREVECAL BIOCHEMISTRY
- PREVECAL PROTEINS
- PREVECAL URINE
- PREVECAL RHEUMA
- PREVECAL BIOCHEMISTRY HUMAN
- PREVECAL ANA
- PREVECAL nDNA
- PREVECAL CELIAC
- PREVECAL ANCA
- PREVECAL COAGULATION
- PREVECAL VETERINARY



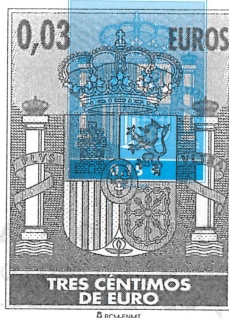
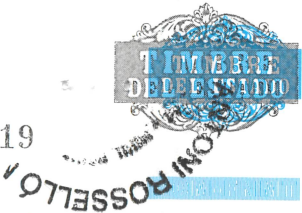
You are hereby advised that:

These products **do not** fall within the scope of Royal Decree 1662/2000, of 29 September, which transposes Directive 98/79/EC of the European Parliament and of the Council, of 27 October 1998, on in vitro diagnosis medical devices, and, consequently, are outside the sphere of competence of this Department of Medical Devices.

They shall be marketed as provided for under the general commercial laws, the laws on protection of users and consumers, and any other specific regulations which are applicable thereto.

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06/2019



CLASE 8.<sup>a</sup>

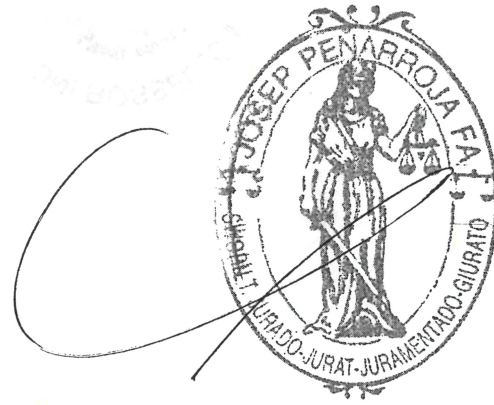
# Traducción Jurada

THE HEAD OF THE DEPARTMENT  
OF MEDICAL DEVICES  
[Signature and seal of the Spanish Medicines  
and Medical Devices Agency]  
Carmen Ruiz-Villar Fernández-Bravo

E-MAIL:  
mpizarro@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8  
28022 MADRID  
TEL: 91 822 50 09  
FAX: 91 822 52 77

[There is a seal which states that the document has been recorded by the Spanish Ministry of Health, dated 20 February 2020]





**TESTIMONIO.- ANTONIO ROSSELLÓ MESTRE**, Notario del Ilustre Colegio de Cataluña, con residencia en Barcelona, -----

**DOY FE:** Que el presente testimonio es fiel reproducción, por fotocopia, del documento original, que me exhibe. Y para que conste libro el presente, extendido en dos folios de papel del Timbre del Estado, exclusivo para Documentos Notariales, serie FA, número el presente y el anterior correlativo en orden ascendente. -----

Barcelona a once de marzo de dos mil veinte. -----

Figura en el libro indicador con el N° 453/2020 de la Sección Segunda.-----



*Antonio Roselló Mestre*