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

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28110 Algete - Madrid
España

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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:

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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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.

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) **CSV: SKRKP3BVBQXJ5G5SN1C9**
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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

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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

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Confirmation Letter Revision History

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

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