

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo II (excepto punto 4) de la Directiva 93/42/CEE
EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex II (except Section 4) of Directive 93/42/EEC

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
2003 11 0365 CT	Desde/From 26-02-2021 Hasta/To 26-05-2024	0318

A favor de/In favour of:

Fabricante/Manufacturer:

Nombre/Name: SIBEL, S.A.U.

Dirección/Address: C/ Rosselló, 500. C.P. 08026 BARCELONA (ESPAÑA)

Representante autorizado ante la UE/Authorized EU representative: Idem

Para el producto/For the product:

Categoría/Category: Productos electromédicos/mecánicos/Electromedical/Mechanical products

Grupo genérico/ Audiómetros/Audiometers

Generic group:

Tipo/Type: Especificado en Anexos de este Certificado/Specified in Annexes to this Certificate

Elaborado en/In the facilities:

Ver Anexo/ See Annex

Fecha inicial/ Initial date: 13-11-2003

Fecha de prórroga anterior/ Previous extension date: 12-11-2018

Este certificado debe ir acompañado por certificado de examen de diseño: NO /This certificate must be accompanied by design examination certificate: NO

Este certificado es consecuencia de la auditoria del sistema completo de garantía de calidad y del examen de la documentación técnica contenida en el expediente nº 95 07 0012, y garantiza que los productos descritos cumplen los requisitos de la Directiva./ This certificate is issued on the full quality assurance system audit, and the examination of the technical documentation contained in dossier nº95 07 0012, and guarantees that the described products fulfils the requirements of the Directive

Madrid, 26 de febrero de 2021

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. Mª Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 26/02/2021

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

CSV: L F C K W 9 Q 2 9 D



CORREO ELECTRÓNICO
on0318@aemps.es

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C/ CAMPEZO, 1 - EDIFICIO 8

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ORGANISMO NOTIFICADO 0318



ANEXO N°/ANNEX NO: I

**CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
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A favor de/In favour of:

Fabricante/Manufacturer:

Nombre/Name: SIBEL, S.A.U.

Dirección/Address: C/ Rosselló, 500. C.P. 08026 BARCELONA (ESPAÑA)

Representante autorizado ante la UE/Authorized EU representative: Idem

Tipo de producto / Devices type: Aparatos de medición de parámetros fisiológicos / Devices for physiological parameters measuring [Código NANDO/NANDO code: MD 1301]

Clasificación/Classification: IIa

1. Productos para audiometría / Audiometry devices

1.1. Audiómetros / Audiometers.

1.1.a. Sibelsound 400 (modelos A, AO, AM, AOM, AOM + y SUPRA) /
Sibelsound 400 (models A, AO, AM, AOM, AOM + and SUPRA).

1.1.b. Sibelsound DUO (modelos A, AOM) / Sibelsound DUO (models A, AOM).

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.

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

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				0318

Instalaciones de fabricación/ Manufacturing Facilities:

Audiómetros fabricados en/ Audiometers manufactured in the facilities:

C/ Rosselló, 500. C.P. 08026 BARCELONA (ESPAÑA)

C/ Passatge Coello, 14. C.P. 08027 BARCELONA (ESPAÑA)

C/ Rec de Dalt, 3, C.P. 08100 Mollet del Vallès, BARCELONA (ESPAÑA)

Madrid, 26 de febrero de 2021

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de
medicamentos y
productos sanitarios**

Fdo. Mª Jesús Lamas Díaz

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Date: 24/05/2024
Reference: SIB019_DEX03_20240524v2
NOTIFIED BODY CONFIRMATION LETTER

SIBEL, S.A.U.
C/ Rosselló, 500. C.P. 08026 BARCELONA
ESPAÑA

NOTIFIED BODY CONFIRMATION LETTER
REFERENCE: SIB019_DEX03_20240524v2

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:

SIBEL, S.A.U.
C/ Rosselló, 500. C.P. 08026 Barcelona
España
ES-MF-000000287

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, 27 de mayo de 2024
Jefa del Centro Nacional de Certificación de Productos Sanitarios



Fdo. Gloria Hernández Hernández



N C P S



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
Transductor desechable Basic UDI-DI: 843603552AESA01101KG	Class IIa	N/A	2003110366CT Epigraph 3.1 NB0318
Transductor desechable con filtro Basic UDI-DI: 843603552AESA01201KM	Class IIa	N/A	2003110366CT Epigraph 3.2 NB0318
Filtro bacteriano-vírico Basic UDI-DI: 843603552AESA01001KB	Class IIa	N/A	2003110366CT Epigraph 4.1 NB0318
SIBEL SOUND 400 Basic UDI-DI: 843603552AAUP00101Q2	Class IIa	N/A	2003110365CT Epigraph 1.1.a NB0318
Sibelsound DUO Basic UDI-DI: 843603552AAUY00101TP	Class IIa	N/A	2003110365CT Epigraph 1.1.b NB0318



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
Datospir Touch Easy-D Basic UDI-DI: 843603552AESP00202RK	Class IIa	N/A	HD 60133106 0001, Product List - nº 1 NB197
Datospir Touch Easy-F Basic UDI-DI: 843603552AESP00202RK	Class IIa	N/A	HD 60133106 0001, Product List - nº 2 NB197
Datospir Touch Easy-T Basic UDI-DI: 843603552AESP00202RK	Class IIa	N/A	HD 60133106 0001, Product List - nº 3 NB197
Datospir Touch Diagnostic-D Basic UDI-DI: 843603552AESP00202RK	Class IIa	N/A	HD 60133106 0001, Product List - nº 4 NB197
Datospir Touch Diagnostic-F Basic UDI-DI: 843603552AESP00202RK	Class IIa	N/A	HD 60133106 0001, Product List - nº 5 NB197
Datospir Touch Diagnostic-T Basic UDI-DI: 843603552AESP00202RK	Class IIa	N/A	HD 60133106 0001, Product List - nº 6 NB197
Módulo Transductor Desechable para Datospir Touch Basic UDI-DI: 843603552AESA00302KM	Class IIa	N/A	HD 60133106 0001, Product List - nº 10 NB197
Módulo Transductor Fleisch para Datospir Touch Basic UDI-DI: 843603552AESA00302KM	Class IIa	N/A	HD 60133106 0001, Product List - nº 12 NB197



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
Módulo Transductor Turbina para Datospir Touch Basic UDI-DI: 843603552AESAO0302KM	Class IIa	N/A	HD 60133106 0001, Product List - nº 11 NB197
Módulo Pim-Pem para Datospir Touch Basic UDI-DI: 843603552AESAO0802LE	Class IIa	N/A	HD 60133106 0001, Product List - nº 8 NB197
Software W20s Basic UDI-DI: 843603552AESS00102SM	Class IIa	N/A	HD 60133106 0001, Product List - nº 13 NB197
Datospir Aira D Basic UDI-DI: 843603552AESP00302RQ	Class IIa	N/A	HD 60133106 0001, Product List - nº 26 NB197
Datospir Aira F Basic UDI-DI: 843603552AESP00302RQ	Class IIa	N/A	HD 60133106 0001, Product List - nº 27 NB197
Datospir Aira T Basic UDI-DI: 843603552AESP00302RQ	Class IIa	N/A	HD 60133106 0001, Product List - nº 28 NB197
Datospir Aira Basic T Basic UDI-DI: 843603552AESP00302RQ	Class IIa	N/A	HD 60133106 0001, Product List - nº 25 NB197
Polígrafo Screen&Go Basic UDI-DI: 843603552APOP00102VT	Class IIa	N/A	HD 60133106 0001, Product List - nº 14 NB197
Polígrafo Sleep&Go A Basic UDI-DI: 843603552APOP00102VT	Class IIa	N/A	HD 60133106 0001, Product List - nº 15 NB197



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
Polígrafo Sleep&Go B Basic UDI-DI: 843603552APOP00102VT	Class IIa	N/A	HD 60133106 0001, Product List - nº 16 NB197
Módulo pulsioximetría XPOD Basic UDI-DI: 843603552APOA00102PQ	Class IIa	N/A	HD 60133106 0001, Product List - nº 18 NB197
Módulo EXG Basic UDI-DI: 843603552APOA00202PV	Class IIa	N/A	HD 60133106 0001, Product List - nº 17 NB197
Software BitmedLab Basic UDI-DI: 843603552APOS00102X2	Class IIa	N/A	HD 60133106 0001, Product List - nº 19 NB197
Somnibel Basic UDI-DI: 843603552ADPP00102P8	Class IIa	N/A	HD 60133106 0001, Product List - nº 20 NB197
Somnibel Pro Basic UDI-DI: 843603552ADPP00102P8	Class IIa	N/A	HD 60133106 0001, Product List - nº 21 NB197
Software SomniLab Basic UDI-DI: 843603552ADPS00102QF	Class IIa	N/A	HD 60133106 0001, Product List - nº 22 NB197



Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/10/30	SIB019_DEX03_20231013v1	Initial issue
2024/05/24	SIB019_DEX03_20240524v2	Addition of the following devices to the list: - Transductor desechable (covered by 2003 11 0366 CT) - Transductor desechable con filtro (covered by 2003 11 0366 CT) - Filtro bacteriano-virico (covered by 2003 11 0366 CT) - SIBEL SOUND 400 (covered by 2003 11 0365 CT) - Sibelsound DUO (covered by 2003 11 0365 CT)

