Date: 14/03/2024
Reference: IBE020_DEX03_240322v2
NOTIFIED BODY CONFIRMATION LETTER

IBERHOSPITEX S.A. Avenida Catalunya. 4
08185-Lliçá de Vall (Barcelona)
ES-MF-000000160

NOTIFIED BODY CONFIRMATION LETTER
REFERENCE: IBE020_DEX03_240322v2

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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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, 22 de marzo de 2024
Jefa del Centro Nacional de Certificación de Productos Sanitarios

Fdo. Gloria Hernández Hernández

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 pplication)	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
ihtDEStiny 8428097DESHS	Class III	Sistema de stent coronario con elución de Sirolimus	CE Certificate nº 2004 03 0427 CT Ep. 2.3 NB nº 0318 CE Certificate nº 2020 07 0933 ED NB nº 0318
Botellas Drenofast 8428097REDON63	Class IIa	N/A	CE Certificate nº 98 05 0091 CP Ep. 1.2.a.2, 1.2.b.2, 1.2.b.4, 1.2.c.2 NB nº 0318
Sondas 8428097DRAIN33	Class IIa	N/A	CE Certificate nº 98 05 0091 CP Ep. 1.3.a NB nº 0318
Agujas 8428097AGUJA22	Class IIa	N/A	CE Certificate nº 98 05 0091 CP Ep. 1.4 NB nº 0318
Tubos accesorios 8428097TUBOSACCPX	Class IIa	N/A	CE Certificate nº 98 05 0091 CP Ep. 1.3.c NB nº 0318
Sistema Drenofast 8428097REDONSYSKU	Class IIa	N/A	CE Certificate nº 98 05 0091 CP Ep 1.2.a, 1.2.b y 1.2.c minus those included in ep. 1.2.a.2, 1.2.b.2, 1.2.b.4, 1.2.c.2 NB nº 0318
Conjunto Sondas + Aguja 8428097DRAINNEEDLEX6	Class IIa	N/A	CE Certificate nº 98 05 0091 CP Ep. 1.3.b NB nº 0318

Device name or Basic UDI-DI (under MDR pplication)	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
Batas estériles TNT 8428097SGOWNSB2	I sterile	N/A	CE Certificate nº 98 05 0092 CP, Ep. 1.1.a NB nº 0318
Oper cat 8428097CATHB	I sterile	N/A	CE Certificate nº 98 05 0092 CP, Ep. 2.3 NB nº 0318
Oper cat classic 8428097CATHB	I sterile	N/A	CE Certificate nº 98 05 0092 CP, Ep. 2.10 NB nº 0318
Oper film protect 8428097OFPKE	I sterile	Apósito de poliuretano transparente con adhesivo acrílico y marco de aplicación	CE Certificate nº 98 05 0091 CP Ep. 2.1 NB nº 0318
Oper dres 8428097DRES89	I sterile	N/A	CE Certificate nº 98 05 0092 CP, Ep. 2.2 NB nº 0318
Oper dres film 8428097DRESFILMFB	I sterile	N/A	CE Certificate nº 98 05 0092 CP, Ep. 2.4 NB nº 0318
Oper film surgical 8428097OFSURG99	I sterile	N/A	CE Certificate nº 98 05 0092 CP, Ep. 2.9 NB nº 0318
Oper strip 8428097STRIPBF	I sterile	N/A	CE Certificate nº 98 05 0092 CP, Ep. 2.6 NB nº 0318

Device name or Basic UDI-DI (under MDR pplication)	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
Oper easy 8428097EASY7H	I sterile	N/A	CE Certificate nº 98 05 0092 CP, Ep. 2.5 NB nº 0318
Bolsas de protección 8428097COVERS6D	I sterile	N/A	CE Certificate nº 98 05 0092 CP, Ep. 1.2 NB nº 0318
Amicath II 8428097AMI257	Class III	Catéter de dilatación y perfusión coronaria Amicath II	CE Certificate nº 99 03 0220 CT, Ep. 5, NB nº0318 CE Certificate nº 2018 08 0874 ED, NB nº0318

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
2024/01/31	IBE020_DEX03_240131v1	Initial issue
2024/03/22	IBE020_DEX03_240322v2	Addition of new products