S.E. Carburos Metálicos, S.A.
Av. de la Fama, 1,
08940 Cornellà de Llobregat, Barcelona. Spain
Additional facilities:
Parque Empresarial Vía Norte (Edificio 3, Planta baja),
C/ Quintanavides, 17, 28050 Madrid. Spain

Gasin II, Gases Industrias, Unipessoal, Lda
Rua do Progresso, 53,
4455-533 Perafita. Portugal

19th April 2023

Confirmation Letter Reference: CLNB1639 - ES/BCN/C300002046

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement 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, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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:

S.E. Carburos Metálicos, S.A.
Av. de la Fama, 1,
08940 Cornellà de Llobregat, Barcelona. Spain
SRN: ES-MF-000003117

Gasin II, Gases Industrias, Unipessoal, Lda
Rua do Progresso, 53,
4455-533 Perafita. Portugal
SRN: PT-MF-000005695

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st 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 SGS Belgium NV 1639,

pp
[Sean Kelly]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI	**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
Medical Gas Pipeline System including Vacuum and AGSS in hospitals and clinics for medical use. Basic UDI-DI S.E. Carburos Metálicos, S.A.: 8420219MGPS3A Basic UDI-DI Gasin II, Gases Industrias, Unipessoal, Lda: 56001449043MGPSM8	Class IIb	N/A	Certificate ES19/86925; NB1639 Certificate ES19/86924; NB1639

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2023/04/19	Version 1	Initial issue

EC Certificate Full Quality Assurance System: Certificate ES19/86924

The management system of

Gasin II, Gases Industrias, Unipessoal, Lda.

Rua do Progresso, 53
4455-533 Perafita. Portugal

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Medical Gas Pipeline System including Vacuum and AGSS in hospitals and clinics for medical use.

Sistemas de distribuição de gases medicinais, vácuo e exaustão de gases anestésicos em hospitais e clínicas para uso médico.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 26 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 15 May 2012
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered ES/MAD 163566

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com