EC Certificate Full Quality Assurance System: Certificate CH19/0965

The management system of

Bien Air Surgery SA

Rue de l'Ouest 2B
CH - 2340 Le Noirmont

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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 11 January 1996
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CH/GE 3302346

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

Bien Air Surgery SA

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).
Issue 1

Detailed scope

• OSSEODOC, OSSEOUNO and OSSEODUO:

Control unit (or called also console) used to pilote a micromotor, including foot control device for: Head & Neck/ENT, spine, cranial, Oral/Maxillofacial and plastic/Reconstructive/Aesthetic surgical procedures

• 80K, BASCH, BASCH1, Rapido and Nano:

Micromotors piloted by a control unit to transform electrical energy to rotational energy, for: Head & Neck/ENT, spine, cranial, Oral/Maxillofacial and plastic/Reconstructive/Aesthetic surgical procedures

• S120 handpiece and instruments for:

Head & Neck/ENT, spine, cranial, Oral/Maxillofacial and plastic/Reconstructive/Aesthetic surgical procedures

• OSSEOSTAP Microdrill system

Foot controlled surgical drill system including: electrical motor handpiece and dedicated sterile reusable burs for:

Head & Neck/ENT surgical procedures

• PMAM, PMRM, PM Fisch handpieces and rotary instruments

Surgical drill handpieces and straight shank rotary instruments including stainless steel burs, tungsten carbide burs, diamond burs, sterile and non-sterile for: Head & Neck/ENT, Oral/Maxillofacial and Plastic/Reconstructive/Aesthetic surgical procedures

• PM2 handpieces and rotary instruments

Surgical drill handpieces and dedicated PM2 shank rotary instruments including stainless steel burs, tungsten carbide burs, diamond burs, sterile and non-sterile and cranio guards for: Head & Neck/ENT, spine, cranial, Oral/Maxillofacial and Plastic/Reconstructive/Aesthetic surgical procedures.

• PMR handpieces, sawblades and microsaws. Surgical handpieces and dedicated reusable sawblades and rasps, for: Head & Neck/ENT, cranial, Oral/Maxillofacial and plastic/Reconstructive/Aesthetic surgical procedures

• PM PERFO handpiece. Non-sterile motorised handpiece for: Cranial surgical procedures

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.

Bien Air Surgery SA
Rue de l'Ouest 2B
2340 Le Noirmont
Switzerland

April 24rd, 2024

Confirmation Letter Reference: CLNB1639 - CH/GE/3205727

To whom it may concern,

Confirmation of receipt 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, 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

Bien Air Surgery SA
Rue de l'Ouest 2B
2340 Le Noirmont
Switzerland
SRN Number (if available): CH-MF-000016376

Bien-Air Surgery SA
Länggasse 56
2504 Bienne/Biel
Switzerland
SRN Number (if available): CH-MF-000016376

Bien-Air Europe Sàrl
Rue du 8 Mai 1945
94110 Arcueil
France
SRN: FR-AR-000011942

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices 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.

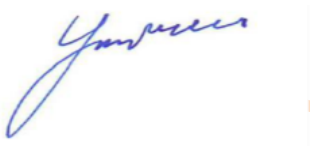
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- 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 NB1639,



pp [Haldun OGUZ]

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

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	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
Origo control unit / 76300555_001_EQ	Class IIa	N/A	OSSEODOC, OSSEOUNO and OSSEODUO/7630055_001_EQ	Certificate CH19/0965/NB1639
PM2 Handpieces / 76300555_009_FG	Class IIa	PM2 handpieces and rotary instruments	N/A	Certificate CH19/0965/NB1639
PM2 Burs / - PM2 single use sterile burs : 76300555_010_ES - PM2 reusable nonsterile burs : 76300555_011_EV	Class IIa	PM2 handpieces and rotary instruments	N/A	Certificate CH19/0965/NB1639
Micromotors / 76300555_002_ET	Class IIa	80K, BASCH, BASCH1, Rapido and Nano	N/A	Certificate CH19/0965/NB1639
Shaver handpiece / 76300555_014_F6	Class IIa	S120 handpiece and instruments	N/A	Certificate CH19/0965/NB1639
Shaver blades and burs / - Shaver sterile single use	Class IIa	S120 handpiece and instruments	N/A	Certificate CH19/0965/NB1639

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
blades : 76300555_016_FC - Shaver sterile reusable blades : 76300555_018_FJ - Shaver sterile single use burs : 76300555_019_FM				
Osseostap Handpiece & foot pedal / - OSSEOSTAP motorized handpiece : 76300555_005_F4 - OSSEOSTAP foot pedal : 76300555_006_F7	Class IIa	Osseostap Microdrill system	N/A	Certificate CH19/0965/NB1639
Osseostap burs / - OSSEOSTAP single use sterile burs : 76300555_007_FA - OSSEOSTAP reusable sterile burs : 76300555_008_FD	Class IIa	Osseostap Microdrill system	N/A	Certificate CH19/0965/NB1639
PM Perfo / 76300555_004_EZ	Class IIa	PM Perfo handpiece	N/A	Certificate CH19/0965/NB1639
PM Intra / 76300555_013_F3	Class IIa	PMAM, PMRM, PM	N/A	Certificate CH19/0965/NB1639

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
		Fisch handpieces		
Cranio Guard/ 76300555_012_EY	Class III	Separated from current MDD TF : PM2 handpieces and rotary instruments	N/A	Certificate CH19/0965/ NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/24	Version 1	Initial issue