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

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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.