

EC Certificate Full Quality Assurance System: Certificate CH12/2036

The management system of

## Bien-Air Surgery SA

Rue de l'Ouest 2b,  
2340 Le Noirmont, Switzerland  
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

Consoles and dedicated micromotors and non-sterile shavers and drills handpieces and dedicated sterile, single and non-single use, shaver blades for bone cutting and drilling and for soft tissue cutting and removal; in the fields of ENT, otoneurology, head & neck, maxillofacial, cranial, spine, hand & foot surgery

Consoles and dedicated micromotors, used with drills and handpieces for bone cutting and drilling and for soft tissue cutting and removal; in the fields of ENT, otoneurology, head & neck, maxillofacial, spine and hand & foot surgery.

Surgical drill handpieces and dedicated and non-dedicated, sterile and non-sterile, single and non single use, burrs for bone cutting and drilling in the fields of ENT, otoneurology, head & neck, maxillofacial, cranial, spine and hand & foot surgery.

Microdrill system and dedicated reusable sterile burrs for bone cutting and drilling in the field of ENT and Otoneurology

Surgical Microsaw handpieces and dedicated and non dedicated re-usable non sterile saw blades and rasps, for bone cutting and rasping in the field of rhinoplasty, ENT, Maxillofacial, and hand & foot surgery.

Surgical powered handpiece and blades for skin grafting

Surgical powered handpiece for the introduction of Kirschner Wires for orthopedic surgery

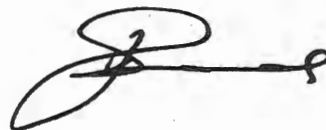
Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 5 October 2015 until 30 November 2018 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 30 November 2016  
Issue 4. Certified since 11 January 1996

Certification is based on reports numbered CH/GE 3302346

Authorised by



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