

Certificate CH12/2037.00

The management system of

# Bien Air Surgery SA

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

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

Design & development, manufacture and sales of consoles, electrical motors, straight and angled handpieces; sterile shaver blades, sterile and non-sterile rotary instruments, non-sterile saw blades and rasps; for bone cutting and drilling and/or for soft tissue cutting and removal; in the fields of ENT, Otoneurology, Head & Neck, Plastic, Maxillofacial, Cranial, and Spine surgery.

Contractor for design & development, manufacture and servicing of consoles, electrical motors, straight and angled handpieces; sterile shaver blades.

This certificate is valid from 30 November 2025 until 30 November 2028 and remains valid subject to satisfactory surveillance audits.

Issue 15. Certified since 30 November 2007

Multiple certificates have been issued for this scope, the main certificate is numbered CH12/2037.00

Certified activities performed by additional sites are listed on subsequent pages.

*L. Moran*

Authorised by

Liz Moran

Business Manager

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - [www.sgs.com](http://www.sgs.com)



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# Bien Air Surgery SA

**ISO 13485:2016**

**EN ISO 13485:2016**

Issue 15

## Sites

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

Manufacture of consoles, electrical motors, straight and angled handpieces; sterile shaver blades, sterile and non-sterile rotary instruments, non-sterile saw blades and rasps; for bone cutting and drilling and/or for soft tissue cutting and removal; in the fields of ENT, Otoneurology, Head & Neck, Plastic, Maxillofacial, Cranial, and Spine surgery.

Contractor for manufacture and servicing of consoles, electrical motors, straight and angled handpieces sterile shaver blades.

Bien Air Surgery SA  
Länggasse 56, CH-2504 Biel/Bienne (Bern), Switzerland

Design & development and sales of consoles, electrical motors, straight and angled handpieces; sterile shaver blades, sterile and non-sterile rotary instruments, non-sterile saw blades and rasps; for bone cutting and drilling and/or for soft tissue cutting and removal; in the fields of ENT, Otoneurology, Head & Neck, Plastic, Maxillofacial, Cranial, and Spine surgery.

Contractor for design & development of consoles, electrical motors, straight and angled handpieces sterile shaver blades.



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