Certificate CH12/2037.00

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

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 01 December 2022 until 30 November 2025 and remains valid subject to satisfactory surveillance audits.

Issue 13. Certified since 30 November 2007

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

Jordhan M. Well

Authorised by Jonathan Hall Global Head - Certification Services





This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



Certificate CH12/2037.00, continued

Bien Air Surgery SA



ISO 13485:2016 EN ISO 13485:2016

Sites

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

Bien Air Surgery SA
Länggasse 56, 2504 Biel/Bienne, Switzerland





This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

