EU Quality Management System Certificate CH23/00001091

The management system of

Bien Air Surgery SA

Rue de l'Ouest 2b, 2340 Le Noirmont, Switzerland
SRN Number: CH-MF-000016376
has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products
Class IIa
MDA0312, MDS1009
ORIGO: Control unit (or called also console) used to pilot a micromotor, including foot control device for: Head & Neck/ENT surgery (otology, rhinology, laryngology), neurosurgery, spine surgery and maxillofacial surgical procedures (UDI-DI 07630055511744; and related Foot Pedal UDI-DI 07630055511751)

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A
Certification is based on following reports: CH/GE/4309241 - S2A 1.2
Authorized representative name and address (if relevant): Bien Air France Rue du 8 May 194594110 Arcueil (France)

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

This certificate is valid from 11 August 2023 until 11 August 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 11 February 2028

Issue 1. Certified since 11 August 2023

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

Authorised by
Virginie Siloret
Global Medical Device Certification Manager

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Bien Air Surgery SA

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Issue 1
Sites
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