

Certificate US26/00000153

The quality management system of

Augurex Life Sciences Corp.

220–887 Great Northern Way, Vancouver, BC V5T 4T5, Canada
Facility number: F009007

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Canada: Medical Device Regulations SOR/98-282, Part 1 - General

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820, Quality Management System Regulation

For the following activities

Design, manufacture, and distribution of in vitro diagnostic devices for the aid in screening, diagnosis, prognosis and monitoring of autoimmune diseases, including rheumatoid arthritis and spondyloarthropathies.

This certificate is valid from Effective date 2026-03-30 until Expiry date 2027-08-15 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 2026-03-30

Issue 1. Organization certified since 2025-10-11 and first certified by SGS on 2026-03-30.



Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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ISO 13485:2016/EN ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities

Design, manufacture, and distribution of in vitro diagnostic devices for the aid in screening, diagnosis, prognosis and monitoring of autoimmune diseases, including rheumatoid arthritis and spondyloarthropathies.

This certificate is valid from 30 March 2026 until 15 August 2027 and remains valid subject to satisfactory surveillance audits.

Issue 1. Organization certified since 23 January 2025 and first certified by SGS on 30 March 2026.

L. Moran

Authorised by

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Business Manager

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