This is to certify that the Quality Management System of:

Purity One Inc. (a division of Hygeniks)

195 Industrial Drive Northampton MA 01060 United States of America

applicable to:

Manufacturer of single use components and assemblies for the biotechnology, biopharma, and pharmaceutical industries.

has been assessed and approved by National Quality Assurance, U.S.A., against the provisions of:

ISO 13485:2016

For and on behalf of NQA, USA



Certificate Number: 22291 EAC Code: 14, 17 Certified Since: December 4, 2020 Valid Until: December 3, 2026 Reissued: February 29, 2024 Cycle Issued: December 4, 2023

Certified by NQA: March 8, 2023

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This approval is subject to the company maintaining its system to the required standard, which will be monitored by NQA, USA, 289 Great Road, Suite 105, Acton, MA 01720, an accredited organization under the ANSI National Accreditation Board.