



Helix Linear Technologies, Inc.  
23200 Commerce Park  
Beachwood, OH 44122

June 5, 2024

Dear Valued Customer,

Thank you for reaching out to us with your supplier survey request. We greatly value our partnership with you and appreciate the opportunity to support your supplier evaluation process.

Due to the high volume of requests, it is unfortunately not feasible for us to complete every individual survey. In an effort to provide you with timely and comprehensive information, we have prepared a general response packet. This packet includes detailed responses to the most commonly asked questions in supplier surveys, ensuring that you have access to the key information needed to evaluate our performance and capabilities.

Should you have any further questions or require specific information that is not included in the packet, please do not hesitate to contact our customer service team at [sales@helixlinear.com](mailto:sales@helixlinear.com) or 855-435-4958. We are always here to assist you and ensure your satisfaction with our services.

Thank you for your understanding and continued partnership. We look forward to continuing to serve you and support your business needs.

Sincerely,

A handwritten signature in black ink that reads "Jeremy Kearns".

Jeremy Kearns  
Director of Quality  
216-485-2232  
Helix Linear Technologies

Enclosures: 4





## **Company Overview**

Helix Linear Technologies operates under a Quality Management System (QMS) to ISO9001:2015 and is currently in process of upgrading to AS9100D, expected Q1 2025. The company maintains essential procedural documentation, including organizational charts, and a quality assurance manual. Helix can provide REACH, RoHS, PFAS, CMRT, Proposition 65, and other regulatory compliance information upon request and has Full Material Disclosure (FMD) capability.

The company's operational structure includes a single shift from 8 AM to 5 PM, Monday through Friday, with a total of 60 employees, 7 in QA, and 8 in engineering.

The management ensures effective communication and implementation of the QMS, with documented job descriptions, quality policies, and regular training programs. Management reviews occur regularly, with evidence of senior management's active participation. The facility allows onsite quality audits and follows a documented procedure for management reviews, ensuring continuous monitoring and improvement of quality objectives.

Document and records control are managed with specific procedures for document control, change control, and record retention. The purchasing process is documented, ensuring that only approved suppliers are used, and all incoming materials are inspected and documented. Traceability procedures are in place for raw materials and components throughout the production process.

Production and process controls include documented procedures for all aspects of production, validation of processes, and preventive maintenance. Calibration and inspection procedures ensure the accuracy and reliability of measuring and testing equipment, traceable to NIST. The facility also has detailed procedures for handling nonconforming products, including corrective and preventive actions to address any issues.

Overall, the company is committed to maintaining high-quality standards, with comprehensive procedures covering all aspects of operations from procurement to production and inspection. Internal audits and management reviews ensure the ongoing effectiveness and suitability of the QMS, supporting the company's ability to meet regulatory requirements and customer expectations.





## **Business Information Summary**

**Company Name:** Helix Linear Technologies, Inc.  
**Year Established:** 2012  
**Federal Tax ID:** 61-1789812  
**Telephone Number:** 855-435-4958  
**D&B Number:** 04-642-0047  
**Company Website:** <http://www.helixlinear.com>  
**CAGE Code:** 6ZYL5  
**Business Classification:** Corporation, Small Business  
**Minority-Owned/Controlled:** No  
**Woman-Owned/Controlled:** No  
**Service-Disabled Veteran-Owned:** No  
**Veteran-Owned:** No  
**HUBZone Certified:** No  
**NAICS Code:** 332721 (For Small Business Certification)  
**ITAR Registered:** Yes  
**CMMC Compliant:** Yes  
**FAR 52.204-21 Compliant:** Yes  
**DFARS 252.204-7012 Compliant:** Yes  
**MLOA Certificate:** Yes  
**DFARS 252.204-7019 and 252-204-7020 Compliant:** Yes

## **Key Contacts**

**Director of Quality:** Jeremy Kearns, [jkearns@helixlinear.com](mailto:jkearns@helixlinear.com), 216-485-2232  
**Sales Manager:** Jeff Keefe, [jkeefe@helixlinear.com](mailto:jkeefe@helixlinear.com), 216-485-2232  
**Customer Service:** Dottie Bewley, [dbewley@helixlinear.com](mailto:dbewley@helixlinear.com), 216-485-2232

**Company Description:** Helix Linear Technologies specializes in the design, manufacturing, and distribution of linear motion technologies, including lead screws, ball screws, and linear actuators. These products serve industries such as industrial, aerospace, and medical devices.

## **Facilities Profile**

**Total Manufacturing Facility Area:** 41,800 sq. ft.  
**Operating Hours:** 1 Shift, 8 AM - 5 PM, Monday to Friday  
**Total Number of Employees:** 60  
**Total Number of QA Personnel:** 7  
**Total Number of Engineering Personnel:** 8  
**Scheduled Annual Shutdowns:** None  
**Union Shop:** No





**SMITHERS**  
QUALITY ASSESSMENTS

## CERTIFICATE OF APPROVAL

This is to Certify that the Quality Management System of:

**Helix Linear Technologies**  
23200 Commerce Park  
Beachwood, OH 44122, USA

has been assessed and approved by Smithers Quality Assessments, Inc., to  
the following quality management system standards and requirements:

### **ISO 9001:2015 with Design**

The Quality Management System is Applicable to:

The Design, Manufacturing, & Distribution of high techlinear motion products including lead  
screw, low or anti backlash nuts, and components  
for the industrial and commercial applications.

Approval Certificate Number: 14.339.2

Original Approval: December 5, 2014

Current Certificate: November 25, 2023

Certificate Expires: November 24, 2026



*The use of the accreditation mark indicates  
accreditation in respect of those activities  
covered by the above certificate number.*

  
on behalf of SQA - J. Michael Hochschwender, CEO

The approval is subject to the company maintaining its system to the required standards which will be monitored by  
Smithers Quality Assessments, Inc., 121 S. Main St. Suite 300, Akron, Ohio, 44308, USA





Dear Valued Customer,

At Helix Linear Technologies, our top priority is to ensure the safety and compliance of our products. We greatly value your interest in our adherence to various regulations, including REACH Article 33 (Candidate List of Substances of Very High Concern for Authorization), Directives 2011/65/EU and 2015/863/EU (3rd amendment to the EU RoHS Directive), REACH Annex-14, REACH Annex-17 and Persistent, Bioaccumulative, and Toxic (PBT) substances restricted under 40 CFR Part 751, subpart E (Regulation of Certain Chemical Substances and mixtures under section 6 of the Toxic Substances Control Act - TSCA).

- REACH Article 33 and RoHS Directives (2011/65/EU and 2015/863/EU): These regulations pertain to the restriction of hazardous substances in electrical and electronic equipment. They aim to limit the use of specific substances of concern to protect human health and the environment.
- REACH Annex-14: This annex under the REACH regulation (EC/1907/2006) outlines the requirements for the registration and evaluation of substances manufactured or imported in the European Union. It focuses on the identification and management of substances of concern.
- REACH Annex-17: This annex addresses the restriction of hazardous substances in specific products or applications. It provides guidelines for the safe use of certain substances to minimize their impact on human health and the environment.
- Persistent, Bioaccumulative, and Toxic (PBT) substances under US CFR 40, Part 751: This regulation falls under the Toxic Substances Control Act (TSCA) in the United States. It focuses on the management and control of substances that are persistent in the environment, bioaccumulative in living organisms, and toxic to human health or the ecosystem.

## Toxic Substances Control Act (TSCA) Compliance Statement

Our operations adhere to the regulations under the Toxic Substances Control Act (TSCA) in the United States. We prioritize the management and control of substances that are persistent, bioaccumulative, and toxic to safeguard human health and the environment.

In addition to the aforementioned regulations, Helix Linear Technologies also addresses the concerns related to PFAS (Per- and Polyfluoroalkyl Substances) and PFOA (Perfluorooctanoic Acid) in our products and manufacturing processes.

PFAS and PFOA are a group of man-made chemicals known for their persistence in the environment and potential adverse effects on human health. We are aware of the growing global attention on these substances and their impact on ecosystems and communities.

As part of our commitment to environmental sustainability, we actively monitor and assess our materials and processes to minimize the presence of PFAS and PFOA in our products. We work closely with our suppliers to ensure that our raw materials and components meet regulatory requirements and adhere to strict quality standards.







## REACH Compliance Statement

Commission Regulation (EU) 2015/830 dated 28 May 2015 and EU 2015/863 amending Regulation (EC) 1907/2006 of the European Parliament and of the Council on REACH released a list of Substances of Very High Concern (SVHC). According to the European Chemicals Agency (ECHA), the 30th update of the REACH Candidate List was published on 27 June 2024. There was one (1) new Substance of Very High Concern (SVHC).

**The number of entries for SVHCs on the Candidate List has increased to 241.**

### EU REACH Substances of Very High Concern (SVHC)

Our H10X™ coated screws contain the below substance(s), present at  $\geq 0.1\%$ , as listed on the REACH Candidate List of Substances of Very High Concern (SVHC) for authorization as of 27 June 2024.

Substance
N-Methyl-2-pyrrolidone

### EU Reach Substances of Concern in Articles (SCIP)

Our H10X™ coating is not an article that is within scope of the SCIP.

### EU Reach Annex XIV – List of substances subject to authorization

This product does not contain any substances on the EU REACH Annex XIV list at  $\geq 0.1\%$ .

### EU Reach Annex XVII – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Our H10X™ coating used on screws is under the scope of the EU REACH Annex XVII. Number(s) on list: 3 75

This product contains the below substance(s) under the scope of the EU REACH Annex XVII:

Substance	Number(s) on list	Intentional substance
Formaldehyde	28 72	No
N-Methyl-2-pyrrolidone	30 71 72	Yes

Reference Annex XVII to Regulation (EC) no 1907/2006 for conditions of restriction associated with the number(s) on the list.





## RoHS Compliance Statement

RoHS 3 Directive (2015/863/EU) of the European Parliament and of the Council of 8 June 2011 on the restriction of certain hazardous substances in electrical and electronic equipment (also known as “RoHS Recast”). Specifically, products manufactured do not contain the substances listed in the table below in concentrations greater than the maximum value below.

Substance	Maximum Limit (ppm)
Lead (Pb)	1000
Cadmium (Cd)	100
Mercury (Hg)	1000
Hexavalent Chromium (Cr6+)	1000
Poly Brominated Biphenyls (PBB)	1000
Poly Brominated Diphenyl ethers (PBDE)	1000
Bis(2-ethylhexyl) phthalate (DEHP)	100
Butyl benzyl phthalate (BBP)	100
Dibutyl phthalate (DBP)	100
Diisobutyl phthalate (DIBP)	100

The conditions of restriction should be assessed for validity according to the end use of the product. Please be aware that the information we are sharing is given in good faith and is based on data we believe to be reliable as of the date of this communication. This information is specific to the material designated herein and sold by Helix Linear Technologies. It does not apply to its use in any process or in combination with any other material. We are providing this information at the request of our customers, and there is no charge for accessing this data.

However, it is essential to understand that since the conditions of use and applications of our products are beyond Helix Linear Technologies' control, we cannot offer any warranties, expressed or implied, regarding the use of this information. Additionally, we assume no liability in connection with any use of our products based on this information.

Please take note that we do not routinely analyze our products for non-intentionally added substances unless it is required for regulatory compliance purposes. For any further inquiries or concerns, please do not hesitate to contact us.

Product Identification: All products manufactured by Helix Linear Technologies.

Date of Issue: 24 October 2024

Jeremy Kearns  
Director of Quality





**United States Department of State**  
*Bureau of Political-Military Affairs*  
*Directorate of Defense Trade Controls*  
*Washington, D.C. 20522-0112*

2024-09-10

[REDACTED]  
HELIX LINEAR TECHNOLOGIES, INC.  
23200 COMMERCE PARK  
BEACHWOOD, OH 44122

**REGISTRANT CODE:** [REDACTED]  
**EXPIRATION DATE: 2025-09-30**

Reference: DDTC Manufacturer Registration Statement and Fee Submission

Dear [REDACTED]

The Office of Defense Trade Controls Compliance (DTCC) received your registration statement and fee to register as a manufacturer. Your registration code is [REDACTED] which expires on 2025-09-30.

Any person who engages in the United States in the business of manufacturing or exporting or temporarily importing defense articles or furnishing defense services is required to register and keep that registration current with this office pursuant to the Arms Export Control Act (AECA) and the International Traffic in Arms Regulations (ITAR). A registration is current if the registration is unexpired and has accurate and up-to-date information.

Registration is a precondition to submitting an application for an export license or other approval from the Directorate of Defense Trade Controls (DDTC) or to use ITAR exemptions but does not confer any export rights or privileges. In addition, if you also plan to engage in brokering activities pursuant to ITAR Part 129, you must register as a broker with DDTC.

As the senior officer empowered to sign the registration statement, you should ensure that your organization maintains records regarding: 1) The senior officer listed on the registration who will oversee the compliance program and be responsible for designating the direct employees who will serve as “empowered officials” for their organization; and 2) The qualified, direct employees who will serve as “empowered officials,” listed by name, position, business unit, phone and fax numbers and email addresses. Please note that third parties (i.e., individuals who are not direct employees, such as consultants, subcontractors, or outside counsel, for example) cannot serve as “empowered officials.”

Also, ITAR Section 122.5 requires you to maintain records concerning your registration and the manufacture, acquisition, and disposition of defense articles; the provision of defense services; and information on political contributions, fees, or commissions furnished or obtained, as required by ITAR Part 130. Records maintained shall be available at all times for inspection and copying by DTCC or Customs officials. To ensure such records are maintained in accordance with ITAR Section 122.5, the organization should provide appropriate training on AECA and ITAR requirements to all employees who will be performing recordkeeping functions and ensure they comply with the ITAR. Ramifications for the failure to comply may include shipment delay and/or shipment seizure by Customs and Border Protection, loss of export privileges, and/or criminal or civil penalties.

Further, if your organization has foreign-person employees, including officers and senior managers,



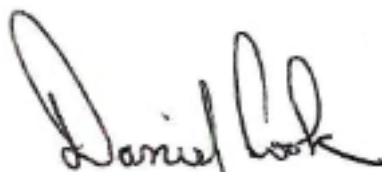
your organization must first obtain a license or other approval before providing such foreign-person employees with access to any ITAR-controlled technical data. It is also prohibited to provide defense services or export defense articles to subsidiaries/affiliates located in proscribed countries under ITAR Section 126.1 (for example, the People's Republic of China, North Korea, Syria, etc.). You should caution your organization's employees not to discuss the substance of ITAR-controlled information with foreign-person employees without first obtaining a license or other approval from DDTC.

You may refer to the DDTC website for a Compliance Guide at <http://www.pmdtdc.state.gov/> and then click on ITAR Compliance tab, next click on How to Comply tab. The DDTC website also includes a copy of the ITAR, explanations of export licensing procedures, how to submit a license application, country sanctions, individuals / companies debarred by the Department of State, and other export matters. The website also includes procedures for requesting a commodity jurisdiction determination (ITAR Section 120.4) should you have doubt as to whether an article, services, or data is covered by the ITAR Part 121 (the U.S. Munitions List).

You may submit your organization's registration renewal up to 60 days before the registration expiration date. At latest, your registration must be received at least 30 days prior to the expiration date to avoid a lapse in registration. You should also ensure your organization's Registration is current before applying for export licenses or other approvals. Also, if appropriate, DTCC requests you to keep your registration information current by submitting amendment requests via DECCS Registration system.

For general registration related questions, please contact the DDTC Response Team at 202-663-1282 or by email at [DDTCCustomerService@state.gov](mailto:DDTCCustomerService@state.gov). For questions related to this matter, please contact Telethia Thomas at 202-632-2153.

Sincerely,

A handwritten signature in black ink that reads "Daniel Cook". The signature is written in a cursive style with a large initial "D" and "C".

Daniel Cook  
Chief, Registration, Compliance, & Analysis  
Office of Defense Trade Controls Compliance