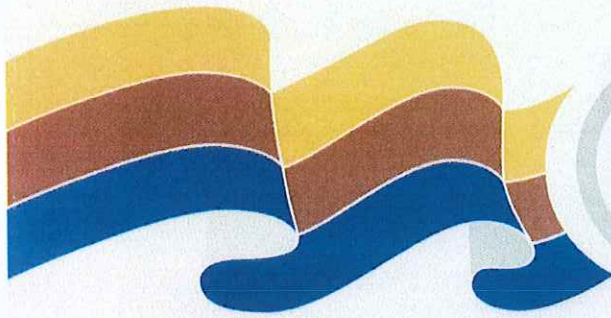


CERTIFICATE OF REGISTRATION



[Handwritten signature]

Having been audited in accordance with requirements of

ISO 13485:2016

**PHÓ GIÁM ĐỐC
TỔNG THỊ BÍCH TUYẾN**

SRI Quality System Registrar, 300 Northpointe Circle, Seven Fields, Pennsylvania, 16046, USA, hereby grants to:

Carclo Technical Plastics

Registration of the management system at its locations:

- Export, Pennsylvania, USA
- Latrobe, Pennsylvania, USA
- Tucson, Arizona, USA
- Derry, New Hampshire, USA

The conditions for maintaining this certificate of registration are set forth in the SRI registration agreements R20.3 and R20.4. Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization.

- Scopes of ISO 13485:2016 registration:** (See registration appendix – pages 2-3)
- Exclusions:** Design and Development
- Initial SRI registration dates:** (See registration appendix – pages 2-3)
- Current registration period:** September 5, 2019 through September 4, 2022

Signed for SRI:

[Signature]
Christopher H. Lake, President & COO

Release Date: September 5, 2019
Certificate Number: 019958
Registration Number: 1504-00-MD



SCOPE OF REGISTRATION



Appendix to the ISO 13485:2016 Certificate of Registration issued to:

Carclo Technical Plastics

6009 Enterprise Drive, Export, Pennsylvania, 15632, USA

Registration # 1504-01

Scope of Registration: "The manufacture of general, non-active, non-implantable medical devices. The manufacture and distribution of in vitro diagnostic instruments. The manufacture of molded plastic components, mechanical subassemblies and electrical subassemblies."

Initial SRI registration date: January 8, 2008

550 Depot Street, Latrobe, Pennsylvania, 15650, USA

Registration # 1504-02

Scope of Registration: "The manufacture of general, non-active, non-implantable medical devices. The manufacture and distribution of in vitro diagnostic instruments. The manufacture of molded plastic components, mechanical subassemblies and electrical subassemblies."

Initial SRI registration date: January 8, 2008

600 Depot Street, Latrobe, Pennsylvania, 15650, USA

Registration # 1504-00

Scope of Registration: "The manufacture of general, non-active, non-implantable medical devices. The manufacture and distribution of in vitro diagnostic instruments. The manufacture of molded plastic components, mechanical subassemblies and electrical subassemblies."

Initial SRI registration date: January 8, 2008

45 Bayhill Drive, Unit A, Latrobe, Pennsylvania, 15650, USA

Registration # 1504-06

Scope of Registration: "The warehousing of general, non-active, non-implantable medical devices. The warehousing of in vitro diagnostic instruments. The warehousing of molded plastic components, mechanical subassemblies and electrical subassemblies."

Initial SRI registration date: August 31, 2015

1141 West Grant Road, Tucson, Arizona, 85705, USA

Registration # 1504-04

Scope of Registration: "The manufacture of general, non-active, non-implantable medical devices. The manufacture and distribution of in vitro diagnostic instruments. The manufacture of molded plastic components, mechanical subassemblies and electrical subassemblies."

Initial SRI registration date: January 8, 2008

Certificate Date: September 5, 2019
Certificate Number: 019958
Registration Number: 1504-00-MD



SCOPE OF REGISTRATION



Appendix to the ISO 13485:2016 Certificate of Registration issued to:

Carclo Technical Plastics

955 West Grant Road, Tucson, Arizona, 85705, USA

Registration # 1504-05

Scope of Registration: "The warehousing of general, non-active, non-implantable medical devices. The warehousing of in vitro diagnostic instruments. The warehousing of molded plastic components, mechanical subassemblies and electrical subassemblies."

Initial SRI registration date: January 8, 2008

925 West Grant Road, Tucson, Arizona, 85705, USA

Registration # 1504-08

Scope of Registration: "The manufacture of general, non-active, non-implantable medical devices. The manufacture and distribution of in vitro diagnostic instruments. The manufacture of molded plastic components, mechanical subassemblies and electrical subassemblies."

Initial SRI registration date: August 31, 2017

1085 West Grant Road, Tucson, Arizona, 85705, USA

Registration # 1504-09

Scope of Registration: "The warehousing of general, non-active, non-implantable medical devices. The warehousing of in vitro diagnostic instruments. The warehousing of molded plastic components, mechanical subassemblies and electrical subassemblies."

Initial SRI registration date: August 31, 2017

22 Manchester Road, Derry, New Hampshire, 03038, USA

Registration # 1504-10

Scope of Registration: "The manufacture of general, non-active, non-implantable medical devices. The manufacture and distribution of in vitro diagnostic instruments. The manufacture of molded plastic components, mechanical subassemblies and electrical subassemblies."

Initial SRI registration date: April 13, 2018

Certificate Date: September 5, 2019
Certificate Number: 019958
Registration Number: 1504-00-MD

