

CERTIFICATE

Certificate Number: 531320.00

The Medical Device Quality Management System and implementation of:

Harbec, Inc.

358 Timothy Lane
Ontario, NY 14519
United States

meets the requirements of the standard:

ISO 13485:2016

Scope:

Plastic injection molding, and CNC machining of medical components.
Manufacturing engineering including design of associated processes, tools,
and programs to support production.

Exclusions:

7.5.5 Particular Requirements for Sterile Medical Devices
7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
7.5.3 Installation activities
7.5.4 Servicing activities

Certificate Expires: December 09, 2022
Certificate Issued: December 18, 2019
Certified Since: December 10, 2016

Last certification cycle expiry date: December 09, 2019
Date of recertification audit: October 11, 2019



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