



CERTIFICATE



This is to certify that

Seaway Plastics Engineering, LLC

6006 Siesta Lane
Port Richey, FL 34668
United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:

The contract manufacture of plastic injection molded components and sub-assemblies, including post molded fabrication for medical devices.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

Certificate registration no.	10013838 MP2016
Date of original certification	2015-05-04
Date of revision	2021-03-12
Date of certification	2021-04-10
Valid until	2024-04-09



DQS Inc.

Brad McGuire
Managing Director





**Annex to certificate
Registration No. 10013838 MP2016**

Seaway Plastics Engineering, LLC

6006 Siesta Lane
Port Richey, FL 34668
United States of America

Location	Scope
10001666 Seaway Plastics Engineering, LLC 16186 Flight Path Drive Brooksville, FL 34604 United States of America	The contract manufacture of plastic injection molding components and sub-assemblies, including post molded fabrication, for medical devices.
10013838 Seaway Plastics Engineering, LLC 6006 Siesta Lane Port Richey, FL 34668 United States of America	The contract manufacture of plastic injection molding components and sub-assemblies, including post molded fabrication, for medical devices.
10015955 Seaway Plastics Engineering, LLC 6041 Siesta Lane Port Richey, FL 34668 United States of America	Receiving, Shipping, Material and Finished Good Storage.
10015956 Seaway Plastics Engineering, LLC 6042 Sherwin Drive Port Richey, FL 34668 United States of America	Assembly, Machining, Inserting, Trimming, Pad Printing, Laser Etching and Packaging of medical components and related accessories.

This annex (edition: 2021-03-12) is only valid in connection with the above-mentioned certificate.