

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
248692-2017-AQ-USA-NA-PS

Initial certification date:
21 April, 2010

Valid:
11 July, 2022 – 10 July, 2025

This is to certify that the management system of
Plexus Services RO S.R.L.
Eugeniu Carada Street, no 2 – 4, Oradea, 410610, Bihor, Romania

has been found to conform to the Quality Management System standard:
ISO 13485:2016

This certificate is valid for the following scope:

The Sale and Distribution of Contract Manufacturing Services, including Production, Test, and Servicing of Printed Circuit Board Assemblies, High Level Assemblies and Finished Devices listed below. High level Assemblies are mechanical, electro-mechanical, pneumatic, optical and packaging types of assemblies. List of Finished Medical Devices manufactured at Plexus Oradea site: - TCM5 continuously monitor tcpO2 for ICU patients. - Infusion pumps

Place and date:
Høvik, 27 June, 2022



For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

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Management Representative