

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

CEA Medical Manufacturing, Inc. d.b.a Biomedical Innovations, Co./USA

(FIN)

Main Site: 1735 Merchants Court, Colorado Springs, CO 80916 United States

Additional site: 1755 Merchants Court, Colorado Springs, CO 80916 United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Contract manufacturing, assembly and packaging of medical products including mechanical, electro-mechanical, plastic devices and cables.

Additional Site1: Manufacturing and distribution

Certificate Number:

0096294

Initial Certification Date:

2019-11-29

Certification Effective Date:

2019-11-29

Certification Expiry Date:

2022-11-28



Intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

