ISO 13485

CERTIFICATE of REGISTRATION

Identification Code: QMSMD0109121107N-002; certified since 2011

Certifies that C-AXIS, Inc.

800 Tower Drive
Hamel, MN 55340

Assessment of the quality management system demonstrates evidence that the processes and activities adhere to regulatory requirements based QSR 21 CFR 820 on sustaining the working scope herein while applying QMS MDD ISO 13485:2016 for regulatory purpose, and inclusive to the protection of communities and consumers. This certification—document is not transferable and remains the property of the international registration body BRS.

Scope of activities: ***Contract manufacturing services for high-end components and solutions to the medical device industry for Class I, II and III devices.***

Date of Effectiveness: 22 December 2020

Date of Renewal: 22 December 2023

An "Annex" document provides validation of this annual certificate—registration, inquire through the organization indicated herein. In matters of protecting client-organizations' privacy and confidentiality, BRS accreditation is U.S. based governmental tripartite authority and aligns with FTC.GOV regulations, and we are not to divulge or share information from assessment-audit activities with external or foreign sources. The assessment audit has been conducted under the supervision of BRS Rim of the World Operations, California USA. BRS North America is an Accredited Unit of Bulltek Registration Services (BRS), U.S.A.

M. Irene Sola—President
BRS Rim of the World Operations
Running Springs, California, USA

28 December 2020

ISO 13485

CERTIFICATE of REGISTRATION

Identification Code: QMSMD0109121107N-002; certified since 2011

Certifies that C-AXIS PR, Inc.

Caguas Oeste Parque Industrial
Carr. PR 156 Km. 58.2, Calle B Lote 22
Caguas, PR 00725

Assessment of the quality management system demonstrates evidence that the processes and activities adhere to regulatory requirements based QSR 21 CFR 820 on sustaining the working scope herein while applying QMS MDD ISO 13485:2016 for regulatory purpose, and inclusive for the protection of communities and consumers. This certification—document is not transferable and remains the property of the international registration body BRS.

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Date of Effectiveness: 22 December 2020
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M. Irene Sola—President
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Running Springs, California, USA

28 December 2020