

Certificate

Quality Management System EN ISO 13485:2016

Registration No.	SX 2216238-1
Certificate Holder	Cretex Medical Component and Device Technologies, Inc. 2840 Research Park Drive Soquel CA 95073 USA
Scope	Contract manufacturing of Sterile and Non-Sterile Custom OEM injection molded components and assemblies for Medical Devices under environmentally controlled conditions

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.	234197867-11
Effective date	2023-04-27
Expiry date	2025-02-17
Issue date	2023-04-27



Aihe Huang

TÜV Rheinland LGA Products GmbH
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2840 Research Park Drive
Soquel CA 95073
USA

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	Cretex Medical Component and Device Technologies, Inc. 2840 Research Park Drive Soquel CA 95073 USA	Activities related to Manufacturing
/02	Cretex Medical Component and Device Technologies, Inc. 3949 Research Park Drive Soquel CA 95073 USA	Activities related to Manufacturing and Distribution
/03	Cretex Medical Component and Device Technologies, Inc. 2880 Research Park Drive Soquel CA 95073 USA	Activities related to Warehousing

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