

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2468805-1

Organization: Cretex Medical Component and
Device Technologies, Inc.
8701 95th Avenue North,
Brooklyn Park, MN 55445
USA

Scope: Contract Manufacture of 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.: 234197100-10
Effective date: 2023-02-10
Expiry date: 2025-02-23
Issue date: 2023-02-10



Aine Huang

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No.	Facility	Scope
/01	c/o Cretex Medical Component and Device Technologies, Inc. 8701 95th Avenue North, Brooklyn Park, MN 55445 USA	Activities related to Manufacturing
/02	c/o Cretex Medical Component and Device Technologies, Inc. 1040 Lund Boulevard, Anoka, MN 55303 USA	Activities related to Manufacturing

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