



America

# CERTIFICATE

Certificate Registration No: S951 21 5425

The Certification Body of  
**TÜV SÜD AMERICA INC.**

Certifies that the organization

**Pivot International**  
11030 Strang Line Rd.  
Lenexa, KS 66215-6900 USA

for the scope

**Contract Design, Engineering, Coordination of Externally Provided  
Manufacturing of Electromechanical Medical Devices with related  
Software / Firmware**

Including the sites see enclosure

has established and applies a Quality Management System.  
An audit was performed and has furnished proof that the requirements according to

## ISO 13485:2016

are fulfilled.

The certificate is valid from December 13, 2023 until December 12, 2026  
With a re-issue date on N/A

Greg Bates  
Director Business Assurance America  
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TÜV SÜD America Inc • 401 Edgewater Place, Suite 500 • Wakefield, MA 01880 USA • [www.TUVSUD.com](http://www.TUVSUD.com)

The validity of this certificate is contingent on the company maintaining its management system to the requirements of the indicated standard and is subject to regular monitoring by TÜV SÜD America.





America

# CERTIFICATE

Certificate Registration No: S951 21 5425

**Certificate Holder:**

**Pivot International**  
 11030 Strang Line Rd.  
 Lenexa, KS 66215-6900 USA

At the Sites	Specific Scope Site
<b>Pivot International</b> 11030 Strang Line Rd. Lenexa, KS 66215-6900 USA	Central function - Contract Design, Engineering, Coordination of externally provided Manufacturing of Electromechanical Medical Devices with Related Software / Firmware
<b>Pivot International</b> 10 F, No. 219, Sec 3 Beixin Rd. Xindian Taipei City, Taiwan Post Code: 23143	Contract Design, Engineering, Coordination of Externally Provided Manufacturing of Electromechanical Medical Devices

  
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 Greg Bates  
 Director Business Assurance America  
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