



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q6 082555 0005 Rev. 03

Holder of Certificate:



PIVOT-HAWKS
MANILA, INC.

PIVOT-HAWKS MANILA, INC.

Unit 1-3, Lot 3D
Greenfield Automotive Park, SEZ
Brgy. Don Jose, Sta. Rosa
4026 Laguna
PHILIPPINES

Certification Mark:



Scope of Certificate:

Production of Motor Control Consoles, Endoscopic Cameras, Drill Drivers (IQ Drill/Drivers), Home Sleep Recorders, Motor Surgical Instrument (Z-Drive), and Surgical Assist Arm for Medical Application

The Provision of Manufacturing Service of Disposable Button for Surgical Assist Arm

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 082555 0005 Rev. 03

Report No.:

724622119

Valid from:

2025-11-25

Valid until:

2028-11-24

Date,

2025-10-13

Christoph Dicks

Head of Certification/Notified Body



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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

PIVOT-HAWKS MANILA, INC.

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Sta. Rosa, 4026 Laguna, PHILIPPINES

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Drivers (IQ Drill/Drivers), Home Sleep Recorders, Motor Surgical
Instrument (Z-Drive), and Surgical Assist Arm for Medical Application

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