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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# C E R T I F I C A T E

## No. QS6 037002 0006 Rev. 01

**Certificate Holder:** **TOYOFLEX CEBU CORPORATION**
Lot 14, Block 2
Cebu Light Industrial Park (CLIP)
Basak
6015 Lapu-Lapu City, Cebu
PHILIPPINES

**Certification Mark:**

**Scope of Certificate:** **Manufacture of Guidewires for the Area of Cardiovascular and Peripheral Vascular**

**Standard(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 037002 0006 Rev. 01
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F006860**
**Report No.:** **MNL20161019110**
**Effective Date:** **2023-09-28**
**Expiry Date:** **2026-07-30**


**Date of Issue:** 2023-10-04

( Renee Walker )
Director, US Certification Body, MHS

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# C E R T I F I C A T E

## No. QS6 037002 0006 Rev. 01

**Regulatory Requirements:** **Audit/Certification Criteria**

**Japan**
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

**United States**
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

**Facility(ies):** **TOYOFLEX CEBU CORPORATION**
Lot 14, Block 2, Cebu Light Industrial Park (CLIP), Basak, 6015
Lapu-Lapu City, Cebu, PHILIPPINES

**Facility Scopes:** Manufacture of Guidewires for the Area of Cardiovascular and Peripheral Vascular
REPs Facility ID: F006860


**Date of Issue:** 2023-10-04

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