



# Certificate

No. Q6 037002 0005 Rev. 04

**Holder of Certificate:** **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 Nonsterile Guidewires and Coronary Angiographic Catheters**  
**Manufacture of Sterile Guidewires and Coronary Angiographic Catheters using Ethylene Oxide Method**  
**The provision of Manufacturing Services of Metal Components for Guidewires**

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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q6 037002 0005 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q6 037002 0005 Rev. 04)

**Report No.:** MNL20161019110\_CN

**Valid from:** 2023-09-27

**Valid until:** 2026-07-27

**Date,** 2023-09-27

Christoph Dicks  
Head of Certification/Notified Body

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## Applied Standard(s):

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

## Facility(ies):

### **TOYOFLEX CEBU CORPORATION**

Lot 14, Block 2, Cebu Light Industrial Park (CLIP), Basak, 6015  
Lapu-Lapu City, Cebu, PHILIPPINES

Manufacture of Nonsterile Guidewires and Coronary Angiographic  
Catheters

Manufacture of Sterile Guidewires and Coronary Angiographic  
Catheters using Ethylene Oxide Method

The provision of Manufacturing Services of Metal Components for  
Guidewires