



NOTICE BELGELENDİRME MUAYENE ve DENETİM HİZMETLERİ A.Ş.

Hereby certifies that

Shunmei Medical Co., Ltd

With the address(es) below:

Head Office: R401 of building B, No.8 of 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China
Address : **Factory:** Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China
Factory: 3rd and 4th Floor, Building 7, Phase II, Innovation and Pioneer Park, Tianyue New District, Pingjiang Country, Yueyang City, Hunan Province

has implemented a quality management system according to

EN ISO 13485:2016

The scope of this Quality Management System includes:

Design & development, manufacturing and sales of medical devices: Guiding Catheter, Hydrophilic Coated Guide Wire, PTCA Guide Wire, Balloon Dilatation Catheter, Angiographic Catheter, Central Venous Catheter Kit, Introducer Sets, Hemodialysis Catheter kits, Hemostasis Valve Set, Guidewires, Introducer Needle, Disposable Pressure Transducers, Connecting Tubing, Angiographic Syringes, Drainage Catheter Kit, Cervical Ripening Balloon, Ureteral Stent Set, Percutaneous Nephrostomy Sets, Postpartum Balloon with Rapid Instillation Components, Dose Control Syringe, Stopcocks, Needle-free Connector, Manifold Kit, Manifolds, Balloon Inflation Devices, TR-closure Band, Microcatheter, Micro Guidewire, Peripheral Guidewire

Certificate Number : ISO.MED.0017.02.2019.RC
Issue Date : 2019.02.11
Reissue Date : 2022.02.15
Validity Date : 2025.02.14
Revision : --
Revision Date : --

Approved by
Özlem VİCDAN AKDAĞ
Chairman of the Board

Signature

According to ISO/IEC 17021 rules, the company is subject to surveillance audits. This certificate is valid as long as the company complies with NOTICE certification rules. You can check the validity of this certificate through contacting the phone number and email address given below. The validity can also be verified via Certificate Query part in our website: www.notice.com.tr

NOTICE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.
Esentepe Mahallesi Milangaz Caddesi No:75/A/92 Kartal / İstanbul / TÜRKİYE
Tel: 00 90 216 504 16 98 – e-posta: info@notice.com.tr



Supplementary Information to ISO.MED.0017.02.2019.RC

Audited Addresses

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|----------------------|---|
| Headquarters | : R401 of building B, No.8 of 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China |
| | : R401 of building B, No.8 of 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China |
| Production | : Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China |
| | : 3rd and 4th Floor, Building 7, Phase II, Innovation and Pioneer Park, Tianyue New District, Pingjiang Country, Yueyang City, Hunan Province |
| Sterilization | : Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China |

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