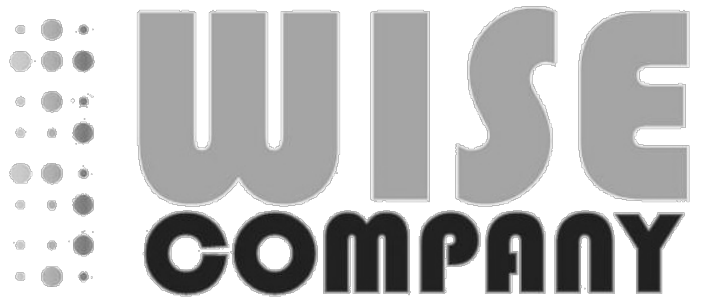




YOUR PLAN WILL SUCCEED WITH.....



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Fax: +82(0)2-865-5442

Homepage: www.wisecompany.org

Product Certification

CE, FDA, CFDA, MHLW, MFDS



1. CE Certification

- Medical Device
- LVD & EMC
- Cosmetic
- Personal protective equipment
- Pressure equipment
- Construction Product
- Machinery
- Marine Equipment
- Recreational craft

2. FDA (U.S.)

- 510K Medical Device
- Registration and Listing
- Cosmetic

3. CFDA (CHINA)

- Medical Device
- Cosmetic

4. MHLW (JAPAN)

- Medical Device
- Cosmetic

5. MFDS (KOREA)

- Medical Device

2

YOUR PLAN WILL SUCCEED WITH.....

System Management

ISO, OHSAS, JGMP, cGMP, KGMP



WISE COMPANY
We provide the BEST solution

1. International Organization for Standardization

- ISO 9001
- ISO 13485
- ISO 14001
- ISO 22000
- ISO 22716
- ISO 50001

2. Occupational Health and Safety Management Systems

- OHSAS 18001

3. Good Manufacturing Practices

- KGMP (KOREA)
- cGMP (U.S.)
- JGMP (JAPAN)

3

YOUR PLAN WILL SUCCEED WITH.....

Product Testing



1. American Society for Testing and Materials
2. British Standards
3. European Committee for Standardization
4. International Electrotechnical Commission
5. German Institute for Standardization
6. Restriction of Hazardous Substances
7. Registration, Evaluation, Authorization and Restriction of Chemicals
8. Calibration

YOUR PLAN WILL SUCCEED WITH.....

Global Service

1. Global Representative Service

- FDA Agent
- EU Representative
- EU Responsible person
- China Medical Device Responsible agent
- China Cosmetic Responsible agent

2. Global Service

- Medical Device registration in EU
- Certificate of Free Sale in EU
- GMDN code
- U. S. D-U-N-S number

WISE COMPANY

Way to enter new market



5

YOUR PLAN WILL SUCCEED WITH.....

Technical Support

WISE CARE SYSTEM

- **Surveillance Care of CE Medical device**
(Risk Management, Clinical Evaluation, Post Market Surveillance)
- **Cosmetic certification package**
(Testing, System Management, Documentation, Representative Service, Registration)
- **Quality Management System and Technical Support**
- **Medical device IEC 60601-1 3rd consultation**
(Testing, Documentation)
- **2rd Party Audit (OEM audit)**

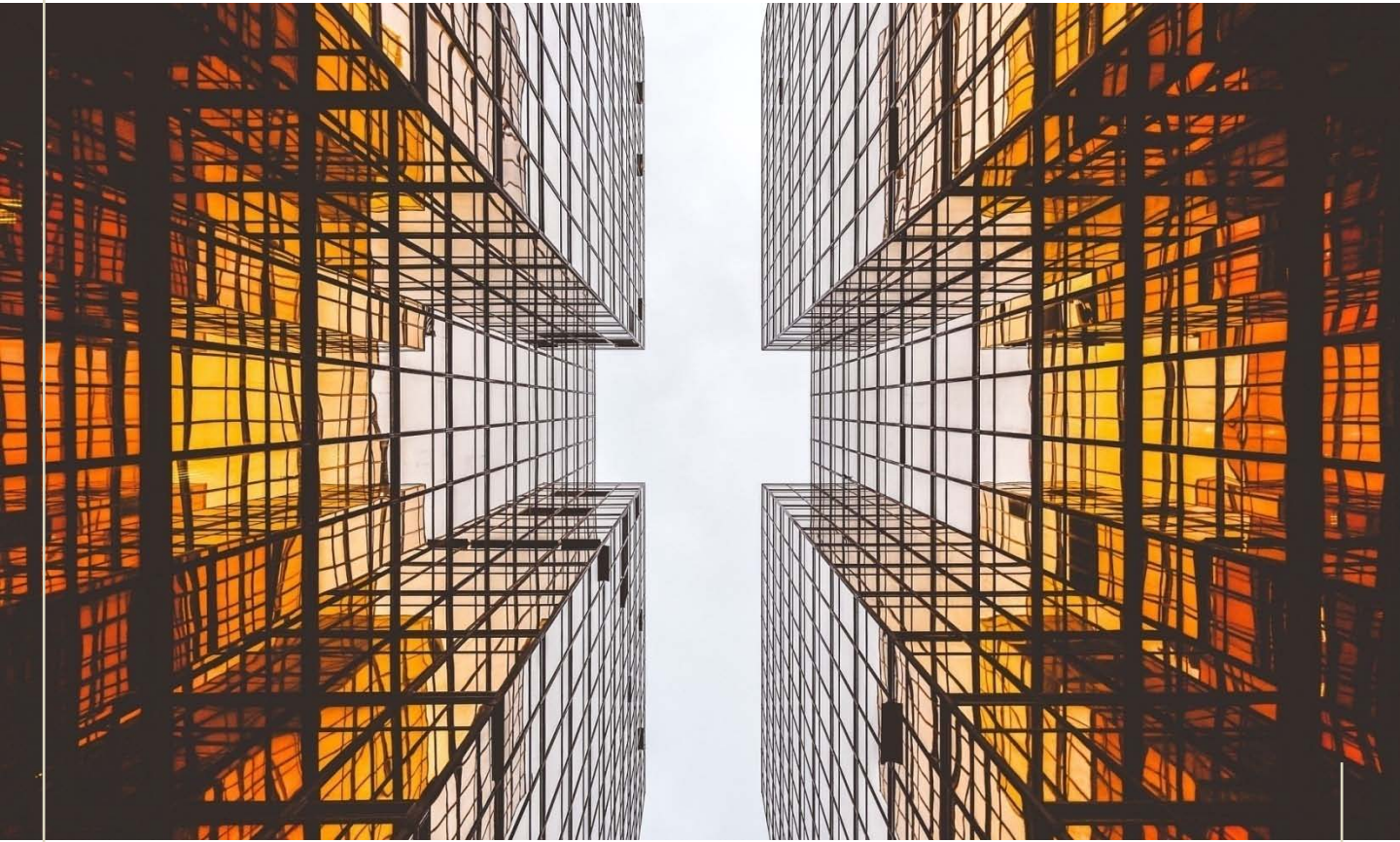


WISE COMPANY

Way to enter new market

6

YOUR PLAN WILL SUCCEED WITH.....



YOUR SUCCESS WILL BE GUARANTEED WITH....



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