

# 跨国企业全球化 过程中的IT实践

**Ambu**

# ZOOM IN

林沪荣

安保（厦门）塑胶工业有限公司

25/112023

# 主题

全球化 **Globalization**

合规 **Compliance**

整合 *Integration*

挑战和机遇 *Challenges and Opportunities*





# 85+ YEARS OF PROVIDING INNOVATIVE MEDTECH SOLUTIONS FOR HEALTHCARE PROFESSIONALS



Dr. Holger Hesse



Founded in 1937 by the engineer, Dr. Holger Hesse



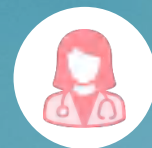
In 1956, Ambu enabled HCPs to provide ventilation in any setting with the self-inflating Ambu bag, a breakthrough innovation still in use today



Launched the world's first single-use bronchoscope in 2009



14 years driving and innovating the single-use endoscopy market



Together with our customers, we rethink solutions to meet the needs of hospitals, clinics and emergency services.

# MEETING CUSTOMER NEEDS AROUND THE WORLD



Direct commercial infrastructure on all major markets with more than 800 employees serving customers



More than 370 employees globally employed in innovation focusing on delivering the newest and best solutions



More than 2,500 employees work in manufacturing to deliver high-quality solutions



4,500 + employees worldwide and growing



## THREE FOCUS AREAS

Ambu provides innovative single-use, sterile solutions for three business areas:

- ➔ ENDOSCOPY SOLUTIONS
- ➔ ANAESTHESIA
- ➔ PATIENT MONITORING

Our solutions are made to:



Optimise workflow & user experience



Reduce costs



Improve patient care

FROST & SULLIVAN

BEST  
2021 PRACTICES  
AWARD

GLOBAL FLEXIBLE SINGLE-USE  
ENDOSCOPE FOR ADVANCED VISUALIZATION  
NEW PRODUCT INNOVATION AWARD

THE WORLD'S MOST  
INNOVATIVE SINGLE-USE  
ENDOSCOPE COMPANY

**Ambu** FOREVER  
FORWARD



reddot winner 2021

**AWARD-WINNING  
PRODUCT DESIGN**

Ambu® aScope™ 4 Cysto &  
Ambu® aScope™ Duodeno

DANISH DESIGN  
AWARD  
WINNER  
2021

**AWARD-WINNING  
PRODUCT DESIGN**

Ambu® aScope™ 4 Broncho Sampler Set

FAST@MPANY



Most Innovative  
Companies 2022

**ADDED TO TOP 10 LIST  
OF MOST INNOVATIVE  
MEDICAL DEVICE  
COMPANIES**

“for scoping out a safer approach  
to endoscopy”



# OUR MANUFACTURING FACILITIES



## Noblesville, USA

Production of breathing bags, circuits and laryngeal tubes



## Penang, Malaysia

Production of Endoscopes, surface electrodes for ECG measurements, neurological surface and needle electrodes



## Xiamen, China

Production of resuscitator, face masks, laryngeal masks, PEEP valves, manometer, neck collars and training manikins



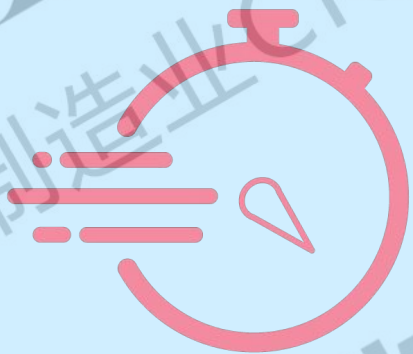
## Mexico

Production of single-use endoscopes within the four major endoscopy segments – pulmonology, urology, ENT and GI as well as products from our anaesthesia portfolio

# 全球化 GLOBALIZATION

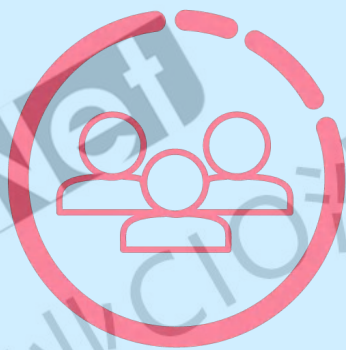


# 全球化 GLOBALIZATION



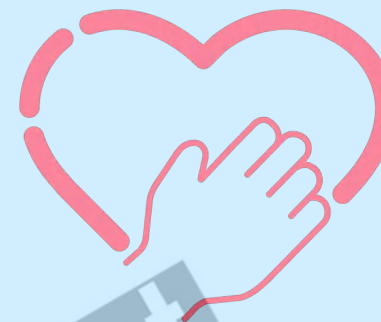
## Globalization 全球化

统一全球网络  
全球核心系统  
全球的服务和支持团队  
服务外包



## Standardization 标准化

IT 基础设施  
软硬件  
操作流程, 技术文档, 配置文件



## Localization 本地化

全球系统本地化  
本地系统  
周边辅助系统/外挂

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合规

COMPLIANCE

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# 合规 COMPLIANCE

- ✓ 符合行业相关的法律法规
- ✓ 各国关于网络安全数据及个人信息的法规
- ✓ 国内网络数据安全及个人信息保护法规



## 符合行业相关的法律法规

Compliance

FDA

EMA

CFDA

ISO 13485

GAMP 5/FDA PART 11

Software Validation





## 各国关于网络安全数据及个人信息的法规

### Private Information

#### GDPR

General Data Protection Regulation  
欧盟《通用数据保护条例》

#### CCPA

California Consumer Privacy Act  
美国加州消费者隐私法

#### PIPEDA

Personal Information Protection and Electronic Documents Act 加拿大个人信息保护与电子文件法



# 国内网络数据安全及个人信息保护法规

## DSL 《中华人民共和国数据安全法》

数据分级分类保护  
数据风险预警  
数据应急处置  
出口管制  
贸易措施  
政务数据安全和开发  
数据违法处罚



## CCSL 《中华人民共和国网络安全法》

公民、法人和其他组织  
网络运营者  
网络产品和服务提供者  
政府部门  
关键基础设施



## PIPL 《中华人民共和国个人信息保护法》



个人信息出境标准合同办法  
标准合同备案 Chinese SCCs  
个人信息安全评估 PIA



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整合

INTEGRATION

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整合

# INTEGRATION

	Orgnization	Resource
America	US/Canada Mexico	Local IT team and Share Center
Asia	China Malaysia Japan India Australia	
EUROPE	Denmark Germany France Italy UK	Corporate IT/Atos



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挑战和机遇

CHALLENGES AND OPPORTUNITIES

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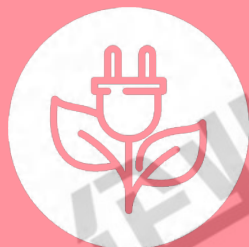
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# 挑战 CHALLENGE



Language  
语言



Culture  
文化



Environment  
环境



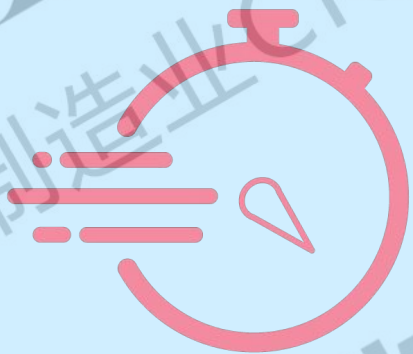
Risk  
政策和法律风险



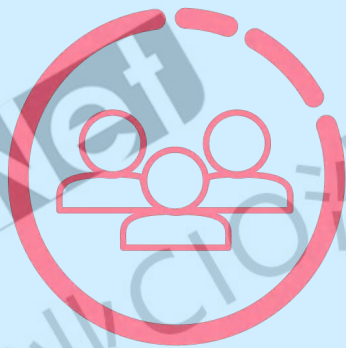
Talents  
人才



# 机遇 OPPORTUNITY



**Efficiency**  
效率



**Flexibility**  
灵活性



**Technology and  
Supplier Chain** 技术和  
供应链能力

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THANK YOU