

此为证书 CN14/10100 译本

下述组织

# 沃芬医疗器械商贸（北京）有限公司

中国北京市朝阳区酒仙桥路 10 号 B18B 座一层 101 室、102 室、103 室及二层 201 室、201A 室、202 室

的管理体系已经过审核，并被证明符合下述要求

**ISO 13485:2016**

**EN ISO 13485:2016**

所涉及的活动范围覆盖

提供体外诊断医疗器械的分销服务，包括采购、进口、销售、安装，售后服务和仓储

该证书的有效期自 2023 年 03 月 26 日 至 2026 年 03 月 25 日 并须经过符合要求的监督审核保持有效

版本号 8. 初始注册日期 2014 年 03 月 25 日  
在其它场所实施的认证活动在后续页面上列出

签署

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ISO 13485:2016  
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版本号 8
<b>场所</b>
中国北京市朝阳区酒仙桥路 10 号 B18B 座一层 101 室、102 室、103 室及二层 201 室、201A 室、202 室
提供体外诊断医疗器械的分销服务, 包括采购、进口、销售、安装和售后服务
中国北京市顺义区顺通路李桥段 68 号院 4 号 1 层 B1、B2、B3、B4、C1、C2、C3、C4 门
提供体外诊断医疗器械的仓储服务



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Certificate CN14/10100

SGS

The management system of

# Werfen Medical Device Trading (Beijing) Company Limited

Room 101, room 102, room 103 of floor 1, Room 201, room 201A, room 202 of floor 2, Block B18B, No. 10, Jiuxiangqiao road, Chaoyang district, Beijing, 100015, P.R. China

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

Provision of Distribution Services Including Purchasing, Import, Sale, Installation, After Sale Service and Warehousing of In Vitro Diagnostic Medical Devices

This certificate is valid from 26 March 2023 until 25 March 2026 and remains valid subject to satisfactory surveillance audits.

Issue 8. Certified since 25 March 2014

Certified activities performed by additional sites are listed on subsequent pages.

*Jonathan M. Hall*

Authorised by  
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**ISO 13485:2016**  
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Issue 8
<b>Sites</b>
Room 101, room 102, room 103 of floor 1, Room 201, room 201A, room 202 of floor 2, Block B18B, No. 10, Jiuxianqiao road, Chaoyang district, Beijing, 100015, P.R. China
Provision of Distribution Services Including Purchasing, Import, Sale, Installation, After Sale Service of In Vitro Diagnostic Medical Devices
Gate B1, B2, B3, B4, C1, C2, C3, C4, floor 1, building 4, Yard No. 68, Liqiao Section, Shunyi District, Beijing, 101300, P.R. China
Provision of Warehousing of In Vitro Diagnostic Medical Devices



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