

Certificate CN19/42044

The management system of

Shenzhen Deda Health Co., Ltd.

Building A5, Sifangpu Street No. 12, Pingdi Street, Longgang District,
Shenzhen City, Guangdong Province, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 9 September 2020 until 8 April 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 7 March 2022
Issue 2. Certified since 9 April 2019

This is a multi-site certification.
Additional site details are listed on the subsequent page.



Authorised by



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SGS United Kingdom Ltd
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HC SGS 13485 2016 0118 M2

Page 1 of 2



Shenzhen Deda Health Co., Ltd.

ISO 13485:2016 EN ISO 13485:2016



Issue 2

Detailed scope

Design, Manufacture and distribution of Oxygen Concentrator and Compressor Nebulizer

Additional facilities

Building 39-1, Dayun Software Town, Longgang Avenue,
No. 8288, Henggang Street, Longgang District,
Shenzhen City, Guangdong Province, P.R. China



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此为证书 CN19/42044 译本
This is an SGS translation of CN19/42044 Issue 2

下述组织

深圳市德达康健股份有限公司

中国广东省深圳市龙岗区坪地街道四方埔街 12 号



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

所涉及的活动范围显示在第二页

该证书的有效期自 2020-09-9 至 2022-04-8
并须经过符合要求的监督审核保持有效
持续认证需在 2022-03-7 之前执行
版本号 2. 初始注册日期 2019-04-9

该证书为多地址证书, 其它具体地址在后续页上列出

签署

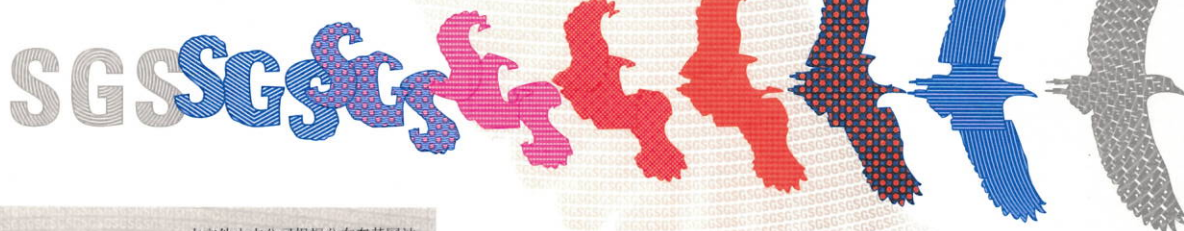


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第 1 页 共 2 页





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This is an SGS translation of CN19/42044 Issue2, Continued

深圳市德达康健股份有限公司

ISO 13485:2016 EN ISO 13485:2016

Issue 2

所涉及的活动范围覆盖

医用雾化器和制氧机的研发、生产和销售

附属机构

中国广东省深圳市龙岗区横岗街道龙岗大道 8288 号
大运软件小镇 39-1 栋



第 2 页 共 2 页

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