北京華科泰生物技術股份有限公司

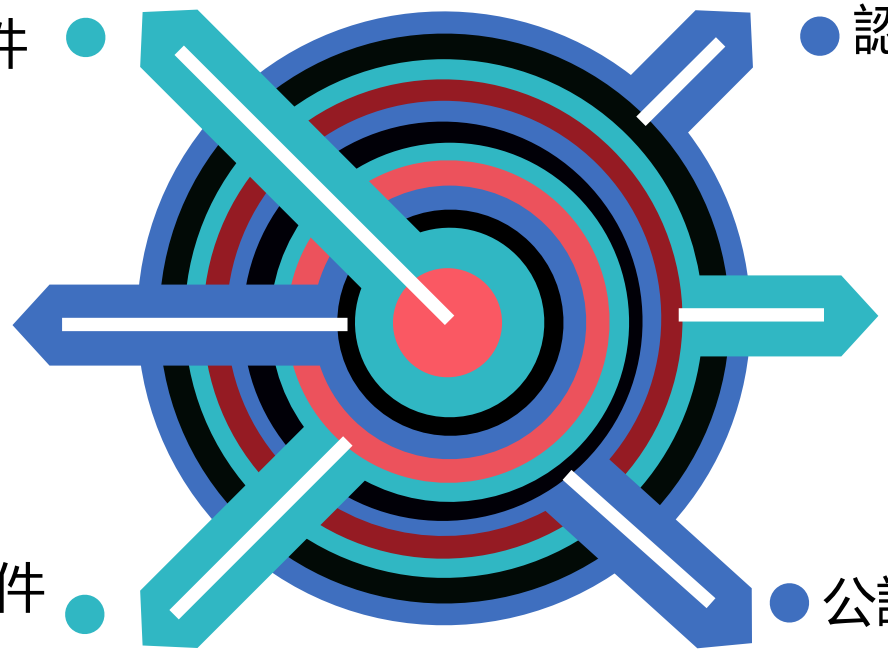
企業紹介

会社紹介

北京華科泰生物技術股份有限公司

- 2007年に設立された、免疫学的定量的検出に焦点を当てたハイテク企業です。
- 「革新と技術、製品の安定性をリードする」というビジネス理念を堅持し、体外診断試薬および機器の研究開発、製造、販売を専門としています。
- 製品の種類は豊富で、現在、化学発光とPOCTの2つの主要な製品ラインと、国内の医療機関であらゆるレベルで広く使用されている108の工業製品があります。
- 350人以上の従業員がおり、そのうち20%が研究開発要員、35%以上が学士以上の従業員、約10%が修士以上の従業員です。
- 強力な科学的研究力により、多くの国内大学、研究機関、医療機関と幅広く緊密な協力関係を築き、IVDキャリアの発展に取り組んでいます。。

知的財産



- 商標：3件
- 認定発明特許：13件
- コンピュータソフトウェアの著作権：13件
- 実用新案特許：5件
- PCT出願段階の特許：1件
- 公認外観特許：1件

医療許可証

医疗器械生产许可证

许可证编号：京食药监械生产许20070105号

企业名称：北京华科泰生物技术股份有限公司

生产地址：地址1：北京市通州区科创东五街2号14幢4层；地址2：北京市通州区科创东五街2号14幢3层F3A；地址3：北京市通州区科创东五街2号14幢1层F1G；地址4：北京市通州区科创东五街2号13幢2层F2C

法定代表人：杨国平

生产范围：2002版分类目录：III类：III-6840 体外诊断试剂；II类：II-6840-3免疫分析系统***

企业负责人：杨国平

住　　所：北京市通州区科创东五街2号14幢4层F4E

发证部门：

有效期限：至 2021 年 08 月 24 日

发证日期：2016 年 08 月 08 日

国家药品监督管理局制

印刷流水号NO 0003523

第二类医疗器械经营备案凭证

备案编号：京通食药监械经营备20170075号

企业名称	北京华科泰生物技术股份有限公司
法定代表人	杨国平
企业负责人	杨国平
经营方式	批发
住 所	北京市通州区科创东五街2号14幢4层F4E
经营场所	北京市通州区科创东五街2号14幢4层F4E-05
库房地址	北京市通州区科创东五街2号14幢4层F4E-03、04
经营范围	2002年版分类目录：II类：6840（诊断试剂除外）*** 2017年版分类目录：II类：22***

备案部门（备案专用章）

备案日期：2019年03月15日

他国での許可

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
Full Quality Assurance Procedures

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to In Vitro Diagnostic Medical Devices.

Reference:	New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography)
Manufacturer's Name:	Beijing Savant Biotechnology Co., Ltd.
Business Address:	14# 4F No. 2 Kechuang East 5th Street, Tongzhou District 101111 Beijing PEOPLE'S REPUBLIC OF CHINA
IVD Medical Device(s):	New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography)
Classification:	Class 3 IVD
GMDN Code and Term:	Severe acute respiratory syndrome-associated coronavirus IVDs (CT772)
Scope of Application:	All batches.

Each kind of IVD medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable classification rules and essential principles, at each stage from the design of the device until its final inspection before being supplied.

This declaration is being made on the basis of the following certificates:

Full Quality Management System Certificate:
EN ISO 13485:2016 (Certificate Number: QS 095022 0002 Rev. 01)
TUV SUD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany

Design Examination Certificate:
n/a

Conformity Assessment Standards Applied:
n/a

Authorised Signatory:

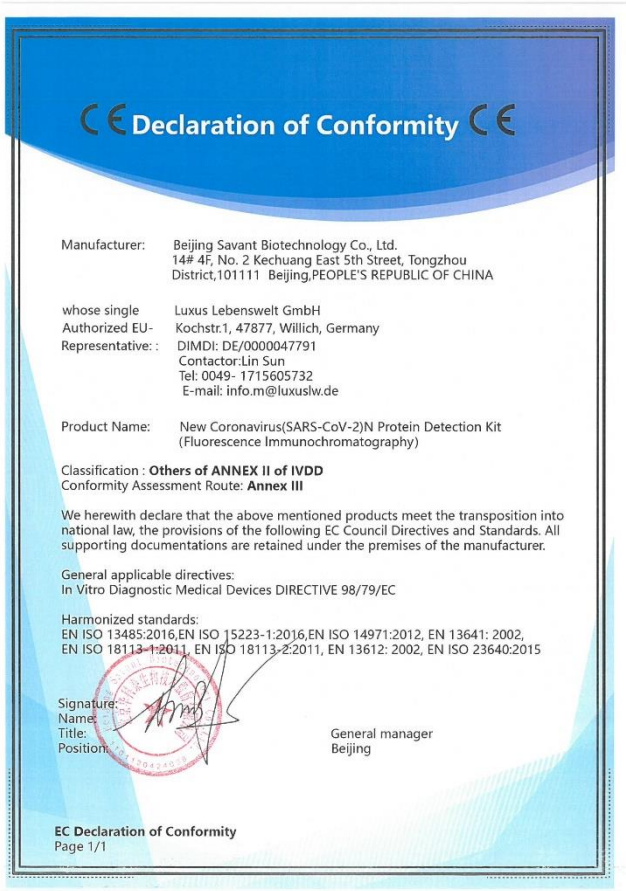
CEO

Name, Position

2020.5.8

Date

オーストラリアTGA



CE Declaration of Conformity CE

Manufacturer: Beijing Savant Biotechnology Co., Ltd.
14# 4F, No. 2 Kechuang East 5th Street, Tongzhou District,101111 Beijing,PEOPLE'S REPUBLIC OF CHINA

whose single Authorized EU-Representative: : Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMDI: DE/0000047791
Contactor:Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

Product Name: New Coronavirus(SARS-CoV-2)N Protein Detection Kit (Fluorescence Immunochromatography)

Classification : **Others of ANNEX II of IVDD**
Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:
EN ISO 13485:2016,EN ISO 15223-1:2016,EN ISO 14971:2012, EN 13641: 2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015

Signature:
Name:
Title: General manager
Position: Beijing

EC Declaration of Conformity
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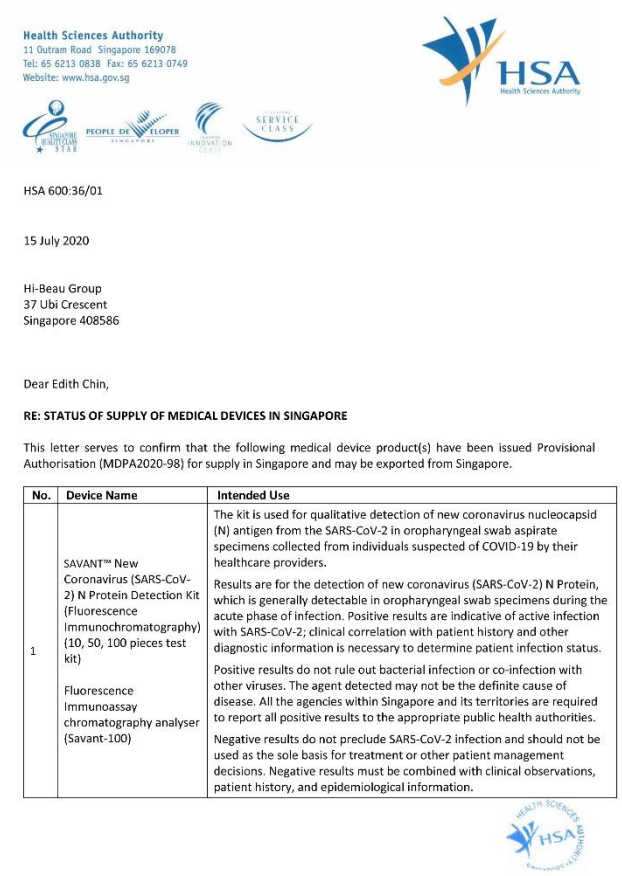
他国での許可



Health Sciences Authority
11 Outram Road Singapore 169078
Tel: 65 6213 0838 Fax: 65 6213 0749
Website: www.hsa.gov.sg

HSA 600:36/01

15 July 2020

Hi-Beau Group
37 Ubi Crescent
Singapore 408586

Dear Edith Chin,

RE: STATUS OF SUPPLY OF MEDICAL DEVICES IN SINGAPORE

This letter serves to confirm that the following medical device product(s) have been issued Provisional Authorisation (MDPA2020-98) for supply in Singapore and may be exported from Singapore.

No.	Device Name	Intended Use
1	SAVANT™ New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography) (10, 50, 100 pieces test kit) Fluorescence Immunoassay chromatography analyser (Savant-100)	The kit is used for qualitative detection of new coronavirus nucleocapsid (N) antigen from the SARS-CoV-2 in oropharyngeal swab aspirate specimens collected from individuals suspected of COVID-19 by their healthcare providers. Results are for the detection of new coronavirus (SARS-CoV-2) N Protein, which is generally detectable in oropharyngeal swab specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV-2; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. All the agencies within Singapore and its territories are required to report all positive results to the appropriate public health authorities. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

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Health Products Regulation Group • Blood Services Group • Applied Sciences Group
A Statutory Board of the Ministry of Health | The Singapore Public Service : Integrity • Service • Excellence

Product Owner: Beijing Savant Biotechnology Co. Ltd
14# 4F, No. 2 Kechuang East 5th Street
Tongzhou District , 101111 Beijing
People's Republic of China

Manufacturing Site: Beijing Savant Biotechnology Co. Ltd
14# 4F, No. 2 Kechuang East 5th Street
Tongzhou District , 101111 Beijing
People's Republic of China

2. The medical device product(s) may be supplied to the healthcare institutions, private hospitals, medical clinics or clinical laboratories licensed under the PHMC Act (Cap. 248) for use on their patients.

3. The medical device product(s) may be exported out of Singapore subject to the duties and obligations as stipulated in the Health Products Act and the Health Products (Medical Devices) Regulation 2010.

4. The confirmation above is subject to the manufacturer's activities conforming to the ISO 13485 quality system.

Yours sincerely,

DR CHRISTOPHER LAM
SENIOR REGULATORY SPECIALIST
For GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

Page **2** of **2**

シンガポールHSA

企業情景-天津工場