CERTIFICAAT EN VERGUNNINGEN

医疗器械生产许可证

许可证编号：皖食药监械生产许 20170033 号

企业名称：合肥康居人智能科技有限公司

生产地址：安徽省合肥市高新区柏堰科技园杭翠路 33 号 4#楼 2 层、6 层

法定代表人：郭本胜

生产范围：Ⅱ类：6804 手术室、急救室、诊疗设备及器具；Ⅱ类：08-05 呼吸、麻醉、急救设备辅助装置

企业负责人：郭本胜

住　　所：安徽省合肥市高新区柏堰科技园杭翠路 33 号 4 栋 3 楼

发证部门：安徽省药品监督管理局

有效期限：至 2022 年 08 月 29 日　发证日期：2020 年 10 月 12 日

国家药品监督管理局制

SGS

VERIFICATION OF EMC COMPLIANCE

Verification No.: SZEM2112010310ATV

Applicant: ANHUI KANGJUREN HEALTH TECHNOLOGY CO., LTD.

Address of Applicant: 3RD FLOOR, BUILDING NO.4, NO.33, GUIJU ROAD HIGH-TECH ZONE, HEFEI, ANHUI PROVINCE, P.R.CHINA, 230088

Manufacturer: ANHUI KANGJUREN HEALTH TECHNOLOGY CO., LTD.

Address of Manufacturer: 3RD FLOOR, BUILDING NO.4, NO.33, GUIJU ROAD HIGH-TECH ZONE, HEFEI, ANHUI PROVINCE, P.R.CHINA, 230088

Factory: ANHUI KANGJUREN HEALTH TECHNOLOGY CO., LTD.

Address of Factory: 3RD FLOOR, BUILDING NO.4, NO.33, GUIJU ROAD HIGH-TECH ZONE, HEFEI, ANHUI PROVINCE, P.R.CHINA, 230088

Product Description: Oxygen Concentrator

Model No.: KJR-11MW

Sufficient samples of the product have been tested and found to be in conformity with

Test Standards: EN IEC 55014-1: 2021
EN 61000-3-3: 2013+A1: 2019
EN IEC 61000-3-2: 2019+A1:2021
EN IEC 55014-2: 2021

As shown in the Test Report Number(s): SZEM2112010310B1

This verification of EMC Compliance has been granted to the applicant based on the results of the tests, performed by laboratory of SGS-CSTC Standards Technical Services Co., Ltd. on the sample of the above-mentioned product in accordance with the provisions of the relevant specific standards under Directive 2014/30/EU.
The CE mark as shown below can be used under the responsibility of the manufacturer after completion of an EU Declaration of Conformity and compliance with all relevant EU Directives.

CE

Kenly Xu
EMC Laboratory Manager

Date: 2021-12-13

Certificate of Compliance

No. 191109122HKT0N

Certificate's Holder: Hefei Kangjuren Intelligent Technology Co., Ltd. Room 803, Block C, Xiangfeng Creative Park, No.211 Xiangfeng Avenue, Hi-tech Zone, Hefei, Anhui

Manufacturer: Hefei Kangjuren Intelligent Technology Co., Ltd. Hefei Jiangchen Park, No.521 Mingchuan Road, Baohe Industrial Park, Hi-tech Zone, Hefei, Anhui

Certification ECM Mark:

Product: Oxygenerator

Model(s): KJR-11, KJR-12, KJR-13, KJR-13, KJR-111, KJR-121, KJR-131, KJR-11SW, KJR-11SW

Verification to: Standard:
EN 60335-1:2012+A11:2014+AC:2014
EN 62233:2008+AC:2008
EN 55014-1:2006+A1:2009+A2:2011
EN 55014-2:1997+A1:2001+A2:2008+AC:1997
EN 61000-3-2:2014, EN 61000-3-3:2013

related to CE Directive(s):
2014/35/EU (Low Voltage)
2014/30/EU (Electromagnetic Compatibility)

Sample: The product has been verified on a voluntary basis, the product(s) satisfies the requirements of the Certification Mark in accordance to the above listed Standard(s). This Device Compliance may not be affixed on the product(s) accordingly to the Mark regulation clause or before any Mark Regulations over the holder of www.globalmark. This Certificate of Compliance can be cross-checked on the Mark of www.globalmark.

This verification scope: Engineering assessment of the construction of the product(s).

Additional Information: clarifications about the CE marking

CE

Date of issue: 23 September 2019

Expiry date: 21 September 2022

Chief Manager

Capacity Manager

Ente Certificazione Macchine Srl

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM CERTIFICATION

This is to Certify that the Quality Management System of

Hefei Kangjuren Intelligent Technology Co. Ltd

Unified Social Credit Code: 91340100MA2N4KJ5XX

Registered Address: 3rd Floor, Building 4, No. 33 Guiju Road, Baohe Science and Technology Park, Hefei High-tech Zone, Hefei City, Anhui Province

Office Address: 3rd Floor, Building 4, No. 33 Guiju Road, Baohe Science and Technology Park, Hefei High-tech Zone, Hefei City, Anhui Province

Permanent Address: 4th Floor, Building 19, No. 40 Qiyun Road, Science and Technology Park, Hefei High-tech Zone, Hefei City, Anhui Province

is in conformity with

GB/T 19001-2016 idt ISO 9001:2015 Standard

The scope of certification is as follows:

Research and Development, Production and Sales of Oxygen Generators and Atomizers Within The Scope of Qualification

Date of initial issuance: 15 Aug 2019

Date of issuance of this certificate: 15 Aug 2019

Certificate validity until: 30 Aug 2022

Issued by:

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM CERTIFICATION

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Hefei Kangjuren Intelligent Technology Co., Ltd

Unified Social Credit Code: 91340100MA2N4KJ5XX

Registered Address: 3rd Floor, Building 4, No. 33 Guiju Road, Baohe Science and Technology Park, Hefei High-tech Zone, Hefei City, Anhui Province

Office Address: 3rd Floor, Building 4, No. 33 Guiju Road, Baohe Science and Technology Park, Hefei High-tech Zone, Hefei City, Anhui Province

Permanent Address: 4th Floor, Building 19, No. 40 Qiyun Road, Science and Technology Park, Hefei High-tech Zone, Hefei City, Anhui Province

is in conformity with

YY/T 0287-2017 idt ISO 13485:2016 Standard

The scope of certification is as follows:

Research and Development, Production and Sales of Oxygen Generators and Atomizers Within The Scope of Qualification

Date of initial issuance: 15 Aug 2019

Date of issuance of this certificate: 15 Aug 2019

Certificate validity until: 30 Aug 2022

Issued by: