

## EU DECLARATION OF CONFORMITY

**Manufacturer:** GUANGDONG KINGFA SCI.&TECH. CO., LT

**Registered office:** NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China

**Authorized representative:** Share Info Consultant Service LLC Repräsentanzbüro

**Registered office:** Heerdter Lohweg 83, 40549 Düsseldorf

**Product name:** Nitrile Examination Gloves

**Name complement:**

**Model name:** KG-1101

**Intended purpose:** Nitrile medical examination gloves are non-sterile and are used for performing medical examinations, diagnostic or therapeutic interventions, and for work with infectious medical material. These protect the patient and the user from contamination. The gloves are intended for single use.

**Risk class of medical device:** Class I

**Risk category of personal protective equipment:** Category III Type B (e.g. KPT)

**Specification:** S, M, L, XL

**Harmonised standards applied:** EN ISO 13485:2016, EN ISO 9001:2015, EN ISO 14971:2019, IEC 62366-1:2015(en), EN ISO 15223-1:2016, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, BS EN 455-4: 2009, EN16523-1:2015+A1:2018, EN ISO 374-1:2016+A1:2018, EN ISO 21420:2020, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016.

The manufacturer declares under its sole responsibility that the characteristics of the above mentioned medical device and personal protective equipment meet all requirements in accordance with Directive 93/42/EEC of the European Parliament and of the Council on medical devices and Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and that this medical device and personal protective equipment is for the intended purpose of use safe, effective, and suitable for the provision of health care. The personal protective equipment type-examination (module B) was performed by the notified body SATRA Technology Europe Ltd. (2777). "EC-Type Certificate Number 2777/15940-01/E00-00".

**Signed for and on behalf of:** GUANGDONG KINGFA SCI.&TECH. CO., LTD.

**(place of issue):** Qingyuan City, Guangdong Province, China

**(date of signature):** 2021-03-12

**(title of signatory):** General Manager

**(signature):** 