DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES

Manufacturer: Qingdao Kingon Medical Science and Technology Co., Ltd

Medical Device: Portable Oxygen Concentrator
Model: P2
Classification - Annex IX: Class IIa, Rule 11
Conformity assessment Route: Annex V

We, Qingdao Kingon Medical Science and Technology Co., Ltd,
Manufacturer Address: Room 301-302, No.15 Hancheng Road,Qingdao Free Trade Zone , shandong,China, 266555
Production Address: 24th Factory Building, NO. 252 Yanhe Road, Huangdao, Qingdao,Shandong, China, 266510
All supporting documentation is retained at the premises of the manufacturer.
European representative: Wellkang Ltd
EC REP
Enterprise Hub North West Business Complex
1 Beraghmore Road, Derry, BT48 8SE
Northern Ireland,UK.

The Kingon declares at our sole responsibility that the product Portable Oxygen Concentrator, model : P2 and belongs to medical device class IIa, rule 11 complies with the requirements of directive 93/42/EEC of 14 June 1993 concerning medical devices; including , at 21 march 2010, the amendments by council directive 2007/47/EEC..

The products comply with requirements of relevant harmonized standards:
EN ISO 13485:2016;EN ISO 14971:2019; EN 1041:2008+A1:2013; EN ISO 15223-1:2016; EN 60601-1: 2006+A1:2013; EN 60601-1-2:2015; EN 62304:2006+A1:2015; EN 62366- 1: 2015; EN 60601-1-6:2010+A1:2015; EN ISO 80601-2-69:2014; EN 60601-1-11:2015; EN 60601 -1-8:2007+A11:2017; EN ISO 10993 -1:2009/AC: 2010; EN ISO 10993 -5 :2009; EN ISO 10993 -10:2013; EN ISO 80601 -2-67:2014; EN 62133 :2015, ISO 18562 -1:2017, ISO

NOTIFIED BODY: **SGS Fimko Ltd**
Takomotie 8 FI-00380 Helsinki, Finland

Identification Number **0598**

(EC) Certificate(s):FI19/07006

Start of CE-marking: 2019.06.09

Date of declaration: **2020.06.09**

Place, Date of Declaration: China Qingdao City **2023.12.15**

青岛精安医疗科技有限责任公司
Qingdao Kingon Medical Science & Technology Co.,Ltd

Signature:

Name: Chu Changpeng
Position: Management representative

Letter of Confirmation #2

23 April 2024

FI24/07172P0

Qingdao Kingon Medical Science and Technology Co., Ltd
Room 301-302(B), No.15 Hancheng Road,
Qingdao Free Trade Zone, Shandong, 266555,
China

Notified Body Letter of Confirmation

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Fimko Ltd, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0598 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Qingdao Kingon Medical Science and Technology Co., Ltd
Room 301-302(B), No.15 Hancheng Road,
Qingdao Free Trade Zone, Shandong, 266555,
China

SRN: CN-MF-000018407

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)

- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Helsinki, 23 April 2024

Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Portable Oxygen Concentrator Model: P2	Class IIa	N/A	FI19/07006, issue 1 NB0598

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A