EC Declaration of Conformity

Manufacturer:

Digitally signed by Maxim Victor
Date: 2021.07.01 12:49:49 EEST
Reason: MoldSign Signature
Location: Moldova

SHENYANG AERTI TECH CO., LTD.
No.77-1, 13th Road, Shenyang Economic & Technological Development Area, Shenyang City, 110027 Liaoning, P.R.China

whose single Authorized Representative:

Well Kang Limited
Company Address: The Black Church, St. Mary's Place,Dublin 7, Ireland
Tel: +353(1)4433560
Fax: +353(1)6864856
Web:www.well-kang.com www.CE-marking.eu
Email: AuthRep@CE-marking.eu

We, the manufacturer, herewith declare that the products

Medical Oxygen Concentrators

Model: AE-3 Model: AE-3-S Model: AE-3-N Model: AE-3-W Model: AE-3-NW,
Model: AE-5 Model: AE-5-S Model: AE-5-N Model: AE-5-W Model: AE-5-NW,
Model: AE-8 Model: AE-8-S Model: AE-8-N Model: AE-8-W Model: AE-8-NW
Model: AR-3 Model: AR-3-N Model: AR-5 Model: AR-5-N

UMDNS-Code: **12873**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: DD 2175876-1
Issue date: 2021-04-07
Expiry date: 2024-05-26

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.
This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above mentioned declaration of conformity is exclusively under the responsibility of

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Address: No.77-1, 13th Road, Shenyang Economic & Technological Development Area, Shenyang City, 110027 Liaoning, P.R.China

2021.4.10
Place, date

Legally binding signature, Function