DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC: 2007/47/EC CONCERNING MEDICAL DEVICES

Manufacturer: Name:JiangSu YuYue Medical Equipment & Supply CO., LTD.
Address: Yunyang Industrial Park, Danyang City, Jiangsu Province , China . 212300

European Representative:
Name: Shanghai International Holding Corp.GmbH(Europe)
Address: Eiffestrasse 80, 20537 Hamburg Germany

Product Name： Oxygen Concentrator
Model: 8F-5AW, 8F-3A, 8F-5A, 9F-3AW

Classification (MDD, Annex IX): IIa (Rule 11)
Conformity Assessment Route: MDD Annex V.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of Council Directive 93/42/EEC: 2007/47/EC concerning medical devices. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC: 2007/47/EC concerning medical devices (MDD 93/42/EEC).

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrabe 65, 80339, MÜnchen, Germany

Identification number: CE0123

(EC) Certificate(s): G2 055329 0025 REV.00

Start of CE Marking: Date CE mark was affixed: 2020-03-30

JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO. LTD
江苏鱼跃医疗设备股份有限公司

Expire date of the Certificate: 2024-05-26

Place, Date of Issue: DanYang, JiangSu , P.R.CHINA 2020-04-08

Name: Bill Wang

Position : Management Representative

LIST OF EU HARMONISED AND INERNATIONAL STANDARDS

S/N	Document No.	Edition	Title
1	93/42/EEC	2007/47/EC	Medical device directives of EU
2	ISO 13485	2016	Medical devices-Quality management systems-Requirements for regulatory purposes
3	ISO 14971	2007	Medical devices - Application of risk management to medical devices
4	EN ISO 10993-1	2009/AC:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing
5	EN ISO 10993-5	2009	Biological evaluation of medical devices – Part 5: Tests doe in vitro cytotoxicity
6	EN ISO 10993-10	2013	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type
7	EN IS0 15223-1	2016	Medical devices - Symbols to be used with medical device Labels, labeling and information to be supplied-Part1: general requirements
8	EN 1041	2008+A1:2013	Information supplied by the manufacturer with medical devices
9	EN 60601-1	2012	Medical electrical equipment - Part 1 : General requirements for basic safety and essential performance
10	EN 60601-1-2	2015	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
11	EN ISO 80601-2-69	2014	Oxygen concentrators for medical use – Safety requirements
12	EN 60601-1-6	2010	Medical electrical equipment -Part I-6: General requirements for basic safety and essential performance -Collateral Standard: Usability

S/N	Document No.	Edition	Title
1	93/42/EEC	2007/47/EC	Medical device directives of EU
2	ISO 13485	2003	Medical devices-Quality management systems-Requirements for regulatory purposes
3	ISO 14971	2000	Medical devices - Application of risk management to medical devices
4	EN ISO 10993-1	2003	Biological evaluation of medical devices – Part 1: Evaluation and testing
5	EN ISO 10993-5	1999	Biological evaluation of medical devices – Part 5: Tests doe in vitro cytotoxicity
6	EN ISO 10993-10	2002	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type
7	EN 980	2003	Graphical symbols for use in the labelling of medical devices

8	EN 1041	1998	Information supplied by the manufacturer with medical devices
9	EN 60601-1	1990 +A1:1993 +A2: 1995 +A3: 1996	Medical electrical equipment – Part 1: General requirements for safety (IEC 60601-1:1998)
10	EN 60601-1-2	2001	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
11	EN ISO 8359	1996	Oxygen concentrators for medical use – Safety requirements
12	EN 60601-1-4	1996 +A: 1999	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems

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