

Declaration of Conformity

Manufacturer: Zhengzhou Olive Electronic Technology Co.,Ltd
5th Floor, Block D,Building 18,Henan International University Science Park
(East District) 450001 Zhengzhou, Henan, PEOPLE'S REPUBLIC OF CHINA

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 München, GERMANY

Product Name: Oxygen Concentrator

Models:

OLV-3,OLV-3W,OLV-5,OLV-5W,OLV-5A,OLV-5AW,OLV-B1,OLV-C1,OLV-8,OLV-10,
OLV-10W,OLV-5S,OLV-5SW,OLV-10S,OLV-10SW

UMDNS Code: 12-873

Classification (MDD, Annex IX):IIa, rule 11

Conformity Assessment Route: Annex V.3

SRN manufacturer: CN-MF-000041995

Basic UDI-DI: 697665349OC6C

We herewith declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr. 65, 80339, München, Germany

Identification number: CE0123

(EC) Certificate(s): G2 103099 0002 Rev.00

Expire date of the Certificate: 2024-04-24

Start of CE Marking: 2019-04-25

Place of Issue: Zhengzhou, CHINA

Date of Issue: 2019-08-05

Signature:

Name: Chen Qiaoxia

Position: General Manager



EC Declaration of Conformity
OLIVE/CE-01 Ver.: B/0