

Declaration of Conformity

Manufacturer:

Name: Jiangsu Konsung Bio Medical Science and Technology Co.,Ltd

Address: No.8, Shengchang West Road, Danyang Economic Development Zone, 212300, Danyang, Jiangsu, China

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European Representative:

Name: Shanghai International Holding Corp.GmbH (Hamburg)

Address: Eiffestrasse 80,20537 Hamburg Germany

Tel: 0049-40-2513175

Fax: 0049-40-255726

Product Name: Oxygen Concentrators GMDN:12873

Classification and relevant Rule of MDD: II a MDD Annex IX, rule 11

Model No: KSOC-5,KSOC-10,KSOW-5,KSU-5**Product Name: Fingertip Pulse Oximeter GMDN: 17148**

Classification and relevant Rule of MDD:IIa MDD Annex IX, rule 11

Model No: Sonosat series include F01LT, F02T,F02P, F03T, F03W,F04T, F04W

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the European Representative.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standard:

All applicable harmonized Standard (published in the Official Journal of the European Communities)

Notified Body Name: SGS Belgium NV, Notified Body 1639

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Notified Body Code: 1639

Certificate No.: CN19/41042

Signature: Xiao Hongjun

Position: General Manager

Date: 2021-3-12

Place: Zhenjiang, China

