DECLARATION OF CONFORMITY

DOC NO.:D-CE-10/20-01-A6

Manufacturer's Name : BLUE SAIL MEDICAL CO., LTD

Manufacturer's Address : No. 21 Qingtian Road, Qilu Chemical Industrial Park,

Zibo, Shandong 255414 China

European Authorized : Lotus NL B.V.

Representative : Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,

Netherlands.

: Tel: 0031 645171879

: Email: peter@lotusnl.com

We declare under our sole responsibility that

The medical device: medical mask

Umdns code:16366

Of class: Class I

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: Directive 93/42/EEC Annex VII

Print Name: Robin Liu

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Designation: RA/QA Manager

Mar 25,2020





