

DECLARATION OF CONFORMITY

DOC NO.: D-CE-10/18-01-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 Representative : Lotus NL B.V.
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,
Netherlands.
: Tel: 0031 645171879
: Email: peter@lotusnl.com
Product Type : Single-use Medical Face Mask
(Distributed under VIRAZON brand by HYGOTREND s.r.o)
Standard : EN 14683: 2019+AC
Device Class : I, Rule I(Annex VIII of MDR)
Conformity Assessment : Article 19, Annex II and Annex III according to REGULATION
(EU) 2017/745
UMDNS Code : 12447
Conformity Route : Self-Declaration

We, the manufacturer, herewith declare with sole responsibility that our products mentioned above meet's the provisions of the REGULATION(EU) 2017/745. We developed, implemented and maintain a documented post- production monitoring process.



Print Name: Robin Liu

Designation: RA/QA Manager

**blue
sail+**
蓝帆医疗



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