

DECLARATION OF CONFORMITY

MANUFACTURER: Create Biotech Co., Ltd.
No.68, Gong 7th Road, Longtan District, Taoyuan City
325, Taiwan

EUROPEAN REPRESENTATIVE: JouMed Technology OÜ
Sepapaja 6, Tallinn 15551, Estonia

PRODUCT: Oxygen Mask

CLASSIFICATION: Class IIa according to rule(s) 2

UMDN CODE: 12448

MODEL: All models

CONFORMITY ASSESSMENT ROUTE: MDD 93/42/EEC, Annex V

WE HEREWITH DECLARE EXCLUSIVELY UNDER SOLE RESPONSIBILITY THAT
ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL
DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION
IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY: TÜV SÜD Product Service GmbH
Ridlerstr. 65 • 80339 München Germany
CE 0123

(EC) CERTIFICATE (S): G2 104204 0004 Rev. 00

START OF CE-MARKING: 2019-10-09

PLACE, DATE OF ISSUE: Taoyuan City, Taiwan / 2019-10-09

SIGNATURE:



Chenyu Jen / General Manager