盈宗製藥有限公司
Profit Royal Pharmaceutical Limited

EU Declaration of Conformity

The manufacturer, or his authorized representative in the Community:

Company: **Profit Royal Pharmaceutical Limited**

Address: **RM 1211, 12/F, Sunbeam Centre, 27 Shing Yip Street, Kwun Tong, Kowloon, HONG KONG.**

Declares that our Surgical Respirator described hereafter

Product Name: **NASK FFP2 Nanofiber SMART Mask (Bactericidal Surgical Respirator)**

Product Code: **M0011**

is in conformity with the provisions of **CE European Regulation:**

- **(MDR) Medical Device Regulation EU 2017 / 745**

and, where such is the case, the national standard transposing harmonized standards of **CE European**:

- **EN14683:2014 Medical face masks – Requirements and test methods** ***(current compliance with norm EN 14683: 2014 and future compliance with norm EN 14683: 2019 as of September 2021)***

where applicable, for MD (Risk Classification: Class I), the manufacturer requested 3rd party LAB including US Nelson LABs (nelsonlabs.com) and HK SGS (sgs.com) to perform tests on the products based on the EN14683 requirement.

Class I Medical Device ("self- assessment") - Performance Level achieved (Type IIR)
[Conformity assessment route according to the MDR Annex II, III and IV]

Rule of Classification: Non-invasive, Inactive (not energy source), Non-sterile, Single-use, Not for measurement
[Class I - according to rule 1 of the MDR Annex VIII Chapter III Section 4.1 about Non-invasive]

Basic UDI-DI: To be assigned (Once Database Platform EUDAMED is available for Class I Device)
[Timeline for the obligation for placing the UDI carrier is 26 May 2025 for Class I Device]

Authorized Representative: GlobalMIND GmbH (address: Ernst-Mantius-Str.11, 21029 Hamburg Germany)

Note: This EU declaration of Conformity is issued under the sole responsibility of the manufacturer.

Name / Signature: Henry Chow

Position: Quality Manager

Date of issue: 2021-04-01

Place of issue: Hong Kong

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