

## **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 3<sup>rd</sup> party LAB including US Nelson LABs (nelsonlabs.com) and HK SGS (sgs.com) to perform tests on the products based on the EN14683 requirement.

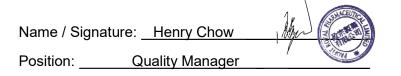
Class I Medical Device ("self- assessment") - Performance Level achieved (Type IIR) [Conformity assessment route according to the MDR Annex II, III and IV]

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.



Date of issue: \_\_\_\_\_2021-04-01

Place of issue: Hong Kong