

Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of directives Medical Devices Directive 2007/47/EC & Personal Protective Equipment Directive 89/686/EEC

Manufacture

Name **DURAPLUS HEALTHCARE**

Address **Address : B-83, Naraina Industrial Area, Phase - 2, New Delhi - 110028, India**

Product **"MANUFACTURING, TRADING, IMPORT, EXPORT OF MEDICAL EQUIPMENTS, MEDICAL DEVICES, SURGICAL EQUIPMENT, DISPOSABLE EQUIPMENTS, SURGICAL EQUIPMENTS, PPE SUITS, PPE KIT, FACE MASK, N95, KN 95, FFP1/FFP2/FFP3 MASK, 3 LAYER MASK, PROTECTIVE, FACE SHIELDS, BIODEGRADABLE BAGS, HAND GLOVES, PROTECTIVE CLOTHING, DISPOSABLE SURGICAL GOWN, PROTECTIVE GOGGLES AND SANITIZER"**

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacturer and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the directives Medical Device Directive 2007/47/EC & Personal Protective Equipment Directive 89/686/EEC.

This certificate is issued under the following conditions:

- It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-Examination procedures, if requested.
- The certificate remains valid until the manufacturing conditions or the quality systems are changed.
- The certificate validity is conditioned by positive results or surveillance audits.
- After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
- The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC declaration of conformity and compliance with all relevant EC directive. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

validity of this certificate can be verified at www.ukmerit.com

DATE OF INITIAL REGISTRATION- **23th May 2020** 1st Surveillance - **22th Apr 2021**
DATE OF CERTIFICATE- **23th May 2020** 2nd Surveillance - **22th Apr 2022**
DATE OF EXPIRY- **22th May 2023**



Authorised Signatory

Certificate Number: 20/AVS/C/2704

Date 23th May 2020

The validity of certificate is subject to regular surveillance audit on or before above mentioned dates and its only valid after successful surveillance with continuation letter issued by UK MERIT. It is issued subject to the continued availability of access at any time and without notice to the above named organization's premises for the purpose of assessment and surveillance regarding the standard named above and UK MERIT terms and conditions.



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