



Certificate of Registration



Reference No	: IAS/IDN/10544
Applicant Name	: PT PRIMA MEDIX NUSANTARA MID PLAZA 2, LT. 8, JL. JENDRAL SUDIRMAN KAV 10-11, Kel. Karet Tengsin, Kec. Tanah Abang, Kota Adm. Jakarta Pusat, Prov. DKI Jakarta, Indonesia.
Type of Product	: Primamedix- SURGICAL MASK EAR LOOP
Directives	: Medical Devices Regulation (EU) 2017/745
Test Standards	: EN 14683:2019
Initial Issue Date	: 22nd Feb 2021*
Certificate Issue Date	: 22nd Feb 2023
Certificate Expiry Date	: 21st Feb 2024*



The product mentioned above complied with the Medical Devices Regulation (EU) 2017/745 and Applicable Standards EN 14683:2019 based on the Technical review. It is the responsibility of the Applicant to ensure that other Applicable European Regulations / Directives are in place to ensure the quality and safety of the product when placing the Product in EU. The certificate is valid for three years (22nd Feb 2021 - 21st Feb 2024) from the date of initial registration limited to the mentioned product. Upon successful completion of the yearly surveillance audit, a new certificate with an extended validity will be issued.





Certifying Authority

