

CERTIFICATE OF REGISTRATION



This is to certify that the management system of

PT BALARAJA METALINDO

Address: Jl. Raya Serang Km. 18.7, Kawasan Industri Purati Kencana Alam (Bonen) No. 33A
Desa Sukanegara, Cikupa, Kec. Cikupa, Kab. Tangerang, Banten 15710

has been registered by TSI as conforming to the requirements of

SNI ISO 13485 :2016

Medical Devices - Quality Management Systems

Scope of Certification :

- Manufacturing of Surgical Mask, Antropometri Set, Hospital Furniture and Personal Health Care
- Assembly of Dry Fog (including its H2O2 Solution), Medical Instrumens, Laboratory Instruments

Authorized Signature

Certificate Reg. Number : MDS18001
Initial Certification Date : 10 January 2018
Certificate Issued Date : 10 January 2024
Certification Validity Date : 09 January 2027
*Certificate Expiry Date : 09 January 2025

President Director

** This certificate will expire unless following audit is performed before this expiry date*



To verify the validity of this certificate please scan the barcode above or send Email to : Info@tsicertification.co.id or call : +62 21-74775110

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ANNEX TO CERTIFICATE – SCOPE OF PRODUCTS

No	Location	No.	Location
1.	Surgical mask : - Surgical Mask Earloop 3PLY - Surgical Mask Headloop 3PLY - Surgical Mask Duckbill 3PLY - Surgical Mask Earloop KF94 - Surgical Mask Headloop KF94 - Surgical Mask Earloop KN95 - Surgical Mask Earloop KN95 Pro	6.	Instrument : - Gunting Benang - Gunting Mayo - Klem U - Nierbeken - Pinset Anatomi Bedah - Klem Alligator - Klem Kasa - Palu Refleks - Klem Mosquito - Forcep Kelly - Baki Instrumen - Tenaculum - Spekulum Vagina (Kecil, Sedang, Besar) - Silinder Korentang - Spatula Lidah - Sonde Uterus - Tampon Tang - Handle Scapel - Sims Vagina Speculum - Gunting Verband - Kocher Forcep - Cheatele Sterilization Forcep - Kaca Laring - Metzenbaum Nelson Dissecting Scissor - Pinset Telinga - Semprit Glycerine - Forcep Bayonet - Eye Speculum - Spekulum Hidung - Magill Forcep - Ear Cannula - Laringoskop (Bayi, Anak, Dewasa) - Hooked Probes - Gunting Verband - Kom Kecil + Tutup - Kom Besar + Tutup - Tromol Kasa
2.	Antropometri Set: - Stadiometer Manual - Stadiometer Digital - Timbangan Dewasa Digital - Timbangan Bayi Digital - Infantometer Board - Pita Lila		
3.	Hospital Furniture: - Baby Basket - Tiang Infus - Tiang Lampu - Instrument Trolley - Emergency Trolley - Verlos Bed - Bed Patient Single Crank - Bed Patient Double Crank - Gynaecology Bed (Obgyn Bed) - Double Bowl Stand - Overbed Table - Bedside Cabinet		
4.	Personal Health Care: - Dry Fog - Thermometer Digital - HB Meter - Penlight - Tensimeter Digital - Pulse Oxymeter		
5.	Laboratory Instrument: - Hematology Analyzer 3 Diff - Urine Analyzer Automated - Centrifuge Mikrohematokrit - Tube Roller Mixer - Mikroskop - Autoclave 18 L - Vaccine Carrier - Vaccine Refrigerator		

Standar : ISO 13485:2016

Reg Number : MDS18001