


**PIHAK BERKUASA PERANTI PERUBATAN (PBPP)
MEDICAL DEVICE AUTHORITY (MDA)**

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|  | GENUINE DIAMOND SDN. BHD. NO. 43B JALAN BP 7/12 BANDAR BUKIT PUCHONG 47120 PUCHONG SELANGOR DARUL EHSAN TEL: +603 – 8069 1111/ 1118 FAX: +603 – 8069 1133 | Person Responsible:- DATO' ANWAR BIN ABDULLAH [info@genuinediamond.com.my] Contact Person:- MS. NUR SYAZA LYANA BINTI MUHAMAD HISHAM [info@genuinediamond.com.my] |
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SCOPE OF REGISTRATION

| No | Scope | Scope Expression |
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| Conformity Assessment of Quality Management System (QMS) | | |
| (1) | GDPMD | Good Distribution Practice for Medical Devices |
| Conformity Assessment of Medical Device Technical Areas | | |
| (2) | MD 0101 | Non-active devices for anesthesia, emergency and intensive care |
| (3) | MD 0102 | Non-active devices for injection, infusion, transfusion and dialysis |
| (4) | MD 0104 | Non-active medical devices with measuring function |
| (5) | MD 0106 | Non-active instruments |
| (6) | MD 0107 | Contraceptive medical devices |
| (7) | MD 0108 | Non-active medical devices for disinfecting, cleaning, rinsing |
| (8) | MD 0202 | Non-active orthopaedic implants |
| (9) | MD 0301 | Bandages and wound dressings |
| (10) | MD 0302 | Suture material and clamps |
| (11) | MD 0303 | Other medical devices for wound care |
| (12) | IVD 0101 | AB0 system |
| (13) | IVD 0201 | HIV infection (HIV 1 and 2) |
| (14) | IVD 0202 | HTLV I and II |
| (15) | IVD 0203 | Hepatitis B, C and D |
| (16) | IVD 0303 | Congenital infections: rubella, toxoplasmosis |
| (17) | IVD 0305 | Human infections: cytomegalovirus, chlamydia |
| (18) | IVD 0307 | Tumoral marker: PSA |
| (19) | IVD 0401 | Clinical chemistry |
| (20) | IVD 0402 | Haematology |
| (21) | IVD 0403 | Immunology |
| (22) | IVD 0404 | Molecular biology |
| (23) | IVD 0405 | Pregnancy and ovulation |
| (24) | IVD 0406 | Specimen receptacles |
| (25) | MDS 7002 | Medical devices utilising tissues of animal origin, including Commission Regulation (EU) No 722/2012 |
| (26) | MDS 7206 | IVDs in sterile condition |
| (27) | MDS 7210 | IVDs utilising material of human origin |
| (28) | VERIFICATION | Conformity Assessment by Way of Verification |