



DEVICE DETAILS

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| NAME OF DEVICE | BI-HAEMOSOL (SOLUTION A) |
| ESTABLISHMENT NAME | DUOPHARMA (M) SDN BHD |
| ROLE OF ESTABLISHMENT | MANUFACTURER |
| REGISTRATION NO | GC364031258019 |
| BRAND NAME | BI-HAEMOSOL |
| MEDICAL DEVICE CATEGORY | MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis |
| DEVICE GROUPING TYPE | FAMILY |
| DEVICE DESCRIPTION | ALMOST COLOURLESS SOLUTION CONTAINING ESSENTIALS SALTS (DIALYSATE); SODIUM CHLORIDE, CALCIUM CHLORIDE, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, GLACIAL ACETIC ACID AND WATER FOR INJECTION. |
| DEVICE INTENDED PURPOSE | BI-HAEMOSOL IS INTENDED AS HEMODIALYSIS SOLUTION WHERE THE PRODUCT IS USED TO REMOVE ACCUMULATED WASTE AND EXCESS WATER FROM THE BODY OF A PERSON WHOSE HAVING DISEASED KIDNEY NOT ABLE TO FUNCTION. INDICATED FOR ACUTE RENAL FAILURE; CHRONIC RENAL FAILURE; OVERHYDRATION; INTOXICATIONS; ADJUSTMENT OF ACID-BASE AND ELECTROLYTE BALANCE. |
| VALIDITY DATE OF REGISTRATION | 28/12/2023 - 27/12/2028 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
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| 1 | BI-HAEMOSOL 1A | BI-HAEMOSOL 1A |
| 2 | BI-HAEMOSOL 2A | BI-HAEMOSOL 2A |
| 3 | BI-HAEMOSOL 3A | BI-HAEMOSOL 3A |
| 4 | BI-HAEMOSOL 5A | BI-HAEMOSOL 5A |