



## DEVICE DETAILS

|                                      |   |
|--------------------------------------|---|
| <b>NAME OF DEVICE</b>                | HYDROCHARGE SURGICAL FACE MASK  |
| <b>ESTABLISHMENT NAME</b>            | CREATIVE CONTRACT (M) SDN BHD   |
| <b>ROLE OF ESTABLISHMENT</b>         | MANUFACTURER  |
| <b>REGISTRATION NO</b>               | GA8148223-132540  |
| <b>BRAND NAME</b>                    | MEDICOS   |
| <b>MEDICAL DEVICE CATEGORY</b>       | SINGLE-USE DEVICES  |
| <b>DEVICE GROUPING TYPE</b>          | FAMILY  |
| <b>DEVICE DESCRIPTION</b>            | - 4-ply Super Soft PP Non-Woven - Latex-Free & Hypoallergenic - Bacterial Filtration Efficiency $\geq 99\%$ - Particle Filtration Efficiency $0.1\mu \geq 99\%$ - Fluid Resistant - Eye-Shield Visor attachment option is available   |
| <b>DEVICE INTENDED PURPOSE</b>       | A surgical mask is used inside the operating room or within other sterile procedure areas to protect the patient environment from contamination. It is also intended to protect the wearer against bacteria, viruses, particles and splashes from potentially contaminated bio-liquids. Regarded as a health practice in healthcare environment against and prevent the spread of diseases (cross-infection). |
| <b>VALIDITY DATE OF REGISTRATION</b> | 26/05/2023 - 25/05/2028   |

## LIST OF DEVICE

| NO | NAME OF DEVICE                 | IDENTIFIER       |
|----|--------------------------------|------------------|
| 1  | HYDROCHARGE SURGICAL FACE MASK | 405X, 406X       |
| 2  | HYDROCHARGE SURGICAL FACE MASK | 415X, 416X       |
| 3  | HYDROCHARGE SURGICAL FACE MASK | 425X, 426X       |
| 4  | HYDROCHARGE SURGICAL FACE MASK | 435X, 436X       |
| 5  | HYDROCHARGE SURGICAL FACE MASK | 405X-7S, 406X-7S |
| 6  | HYDROCHARGE SURGICAL FACE MASK | 415X-7S, 416X-7S |
| 7  | HYDROCHARGE SURGICAL FACE MASK | 425X-7S, 426X-7S |
| 8  | HYDROCHARGE SURGICAL FACE MASK | 435X-7S, 436X-7S |