



## DEVICE DETAILS

|                               |  |
|-------------------------------|--|
| NAME OF DEVICE                | Sentinex Surgical Face Mask  |
| ESTABLISHMENT NAME            | NYPRAX BUSINESS SOLUTIONS  |
| REGISTRATION NO               | GA7403822-90575  |
| BRAND NAME                    | Sentinex   |
| DEVICE GROUPING TYPE          | FAMILY   |
| DEVICE DESCRIPTION            | The flat-folded rectangular disposable face masks have three horizontal, adjacent folds in the middle area, which open up in a cup-shaped manner when used and thus cover the nose and mouth area of the face.   |
| DEVICE INTENDED PURPOSE       | Surgical face masks are intended to prevent the transfer of bacteria and particles from the mouth and facial areas of OR staff to the patient. The surgical masks can also be worn by medical professionals in the outpatient areas, in particular in epidemic or pandemic situations, to reduce the risk of spreading infections. |
| VALIDITY DATE OF REGISTRATION | 18/04/2022 - 17/04/2027  |

## LIST OF DEVICE



| NO | NAME OF DEVICE  | IDENTIFIER |
|----|---|------------|
| 1  | Sentinex Lite Surgical Face Mask, blue                          | 11983      |
| 2  | Sentinex AntiFog Surgical Face Mask, for spectacle-wearers      | 11986      |
| 3  | Sentinex Safety Shield Surgical Face Mask, with visor           | 11989      |
| 4  | Sentinex Lite Surgical Face Mask, green                         | 11991      |
| 5  | Sentinex Lite EL Surgical Face Mask, with ear loops             | 11992      |
| 6  | Sentinex Classic Surgical Face Mask, high filtration efficiency | 11996      |
| 7  | Sentinex SuperSoft Surgical Face Mask                           | 11997      |
| 8  | Sentinex ExtraTouch Surgical Face Mask, with horizontal ties    | 11998      |
| 9  | Sentinex Ultra Surgical Face Mask                               | 11999      |
| 10 | Sentinex Safety   | 32987      |
| 11 | Sentinex Lite EL Surgical Face Mask, with ear loops             | 180100     |
| 12 | Sentinex Lite Surgical Face Mask, blue                          | 180101     |