



DEVICE DETAILS

NAME OF DEVICE	Sentinex Surgical Face Mask
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA7403822-90575
BRAND NAME	Sentinex
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
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

NO	NAME OF DEVICE	IDENTIFIER
11	Sentinex Lite EL Surgical Face Mask, with ear loops	180100
12	Sentinex Lite Surgical Face Mask, blue	180101



MEDICAL DEVICE AUTHORITY