


# Product Data Sheet

SOFT NITRILE BLUE, LATEX - FREE, POWDER - FREE

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## GENERAL INFORMATION

| REF    | PRODUCT DESCRIPTION |   | C = MP Class<br>R = Rule | UMDNS | Personal protection Cat. | Notified Body | PHOTO   |
|--------|---------------------|---|--------------------------|-------|--------------------------|---------------|---|
| 8000SB | S                   | Medical gloves for single use, intended to protect both the wearer and the patient from cross-contamination caused by microorganisms. | CI - R1, R5              | 11882 | III                      | CE            |  |
| 8100SB | M                   |   |                          |       |                          |               |   |
| 8200SB | L                   |   |                          |       |                          |               |   |
| 8300SB | XL                  |   |                          |       |                          |               |   |

| Physical Dimensions   |             | Physical Properties    |              |             | Physical Dimensions          |             | Physical Properties       |              |             |
|-----------------------|-------------|------------------------|--------------|-------------|------------------------------|-------------|---------------------------|--------------|-------------|
| Glove Length (mm)     | ≥ 230       | Test                   | Before Aging | After Aging | Median glove length (mm)     | ≥ 240       | Test                      | Before Aging | After Aging |
| Palm Thickness (mm)   | 0.07 ± 0.02 | Tensile strength (MPa) | ≥ 18         | ≥ 16        | Median palm thickness (mm)   | 0.07 ± 0.02 | Median Force at break (N) | ≥ 6          | ≥ 6         |
| Finger Thickness (mm) | 0.09 ± 0.02 | Elongation (%)         | ≥ 500        | ≥ 400       | Median finger thickness (mm) | 0.09 ± 0.02 |                           |              |             |

|                        |  |
|------------------------|--|
| Regulatory Compliance: | MDR 2017/745, MDD 93/42/EEC  |
| Standards:             | EN 455 - 1, 2, 3, 4, EN 374 - 1, 2, 4, 5, EN 16523 - 1, EN 420 + A1 and EU 2016/425  |
| Classification:        | Class I (MDR 2017/745), Class I (MDD 93/42/EEC), Category III (EU 2016/425)          |
| Application Settings:  | Low risk - medical, dental, patient care, aged care, pathology lab and food handling |

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