



# Asther Nitrile Examination Gloves

## Technical Data Sheet

### General Information

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<b>Type:</b>	Single use examination protective glove, disposable, non-sterile
<b>Labelling:</b>	Information printed on dispenser box
<b>Shape:</b>	Ambidextrous - straight fingers
<b>Material:</b>	Nitrile Synthetic Rubber (not made with natural rubber latex)
<b>Colour:</b>	Blue
<b>Inside:</b>	Powder free
<b>Outside:</b>	no treatment
<b>Cuff/Surface:</b>	Beaded cuff / finger textured
<b>Shelf life:</b>	3 years
<b>Sizes:</b>	S, M, L, XL

### Dimensions, physical properties and biocompatibility

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DIMENSIONS	Standards
	Asther Glove
Length (mm)	230 min
Width (mm)	75 ± 5 (XS) 85 ± 5 (S) 95 ± 5 (M) 105 ± 5 (L) 115 ± 5 (XL)
Thickness- Single wall (mm)	Fingers: 0.08 mm min  Palm: 0.06 mm min

Tensile	<b>Tensile strength (MPA)</b> Before aging: 18Mpa min After aging: 20Mpa min  <b>Elongation at break (%)</b> Before aging: 500% min After aging: 400% min
Powder Content	1 mg/glove maximum
Protein Content	Free Protein



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#### ***Performance requirements and inspection levels***

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**Freedom from holes (Barrier)** AQL  $\leq$  1.5  
(as per EN 455-1, sampling in accordance with ISO 2859-1, G-1)

**Dimensions and physical properties** AQL 4.0  
(as per ASTM D6319, sampling in accordance with ISO 2859-1, S-2)

#### ***Standards, guidelines & quality certificates***

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**Quality certification** - ISO 9001, ISO 13485

**Conformity to regulations** - FDA, CE  
- Medical Device Regulation (EU) Directive 93/42/EEC: Class I

**Conformity to standards** - EN ISO 374-1, EN 374-2, EN 16523-1, EN 374-4, EN ISO 374-5;  
- ISO EN 21420, ISO 16604 : 2004, EN 455-1, EN 455-2, EN 455-3, EN 1186



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### ***Instructions and additional statements***

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<b>Storage instruction</b>	Store in original packaging in a dry and dark place at 10 °C to 30 °C. Refer to guidelines of storage of rubber products as described in ISO 2230:2002. Ensure that storage area is kept cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper ions discolour the glove.
<b>Cautionary statement and ingredient information</b>	Protect gloves against ultraviolet light sources, such as sunlight and oxidizing agents. Storage above 30 °C will lead to accelerated aging and should be avoided. This product contains accelerators (Dithiocarbonate types, Zinc- mercaptobenzothiazol) not to be used in a hypersensitivity of these substances. For further information, a list of substances contained in the glove is available upon request.

### ***Reporting System***

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<b>Medical device vigilance and reporting system</b>	According to the official reporting criteria of the Medical Device Regulation, incidents caused by examination gloves must be reported immediately to our Medical Device Reporting team. E-Mail: <a href="mailto:sales@asthersupplies.com">sales@asthersupplies.com</a>
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<b>Remark</b>	Replaces all previous versions. All standards reference refers to the date of document issue.
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