Asther Nitrile Examination Gloves
Technical Data Sheet

General Information

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

Dimensions, physical properties and biocompatibility

DIMENSIONS	Standards
	Asther Glove (long cuff)
Length (mm)	280 ± 10 min (XS, S) 290 ± 10 min (M, L, XL)
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	Tensile strength (MPA) Before aging: 18Mpa min After aging: 20Mpa min Elongation at break (%) 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

Freedom from holes (Barrier) AQL <= 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

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

Storage instruction	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.
Cautionary statement and ingredient information	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

Medical device vigilance and reporting system	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: sales@asthersupplies.com

Remark Replaces all previous versions. All standards reference refers to the date of document issue.