

SENTINA® AZURE NITRILE

Examination Gloves Nitrile, non-sterile

REF 155360-155364

August 2022

1. Composition of the Product

SENTINA® AZURE NITRILE examination gloves consist of:

- acrylonitrile butadiene rubber (NBR)

Note: The product contains dithiocarbamates – do not use in case of intolerances.

This product data sheet covers the following items:

REF	Product Description	Size
155360	SENTINA® AZURE NITRILE examination gloves nitrile, non-sterile	XS (5-6)
155361	SENTINA® AZURE NITRILE examination gloves nitrile, non-sterile	S (6-7)
155362	SENTINA® AZURE NITRILE examination gloves nitrile, non-sterile	M (7-8)
155363	SENTINA® AZURE NITRILE examination gloves nitrile, non-sterile	L (8-9)
155364	SENTINA® AZURE NITRILE examination gloves nitrile, non-sterile	XL (9-10)

2. Packaging / Structure and Composition

2.1 Unit container

See 2.2

2.2 Shelf Container

1 folding box consisting of cellulose, size 231x126x62mm.

2.3 Transit Container

1 corrugated cardboard box consisting of cellulose, size 315x258x245mm.

2.4 Packaging Units Shelf Container and Transit Container

REF	SC	TC
155360	100 pieces	1.000 pieces
155361	100 pieces	1.000 pieces
155362	100 pieces	1.000 pieces
155363	100 pieces	1.000 pieces
155364	100 pieces	1.000 pieces

3. Manufacture

SENTINA® AZURE NITRILE examination gloves are produced according to specification and hygienic conditions and packed as described in its relevant packaging specification.

4. Description

SENTINA® AZURE NITRILE examination gloves are blue gloves that can be used on both sides. The product is available in different sizes.

5. Properties

SENTINA® AZURE NITRILE examination gloves are liquid-tight, tear resistant and powder-free. They are suitable for food contact.

Natural rubber latex is not an intentional ingredient in the production of the above mentioned products. However, to the best of our knowledge we cannot completely exclude any potential contaminations with latex traces from the production or the environment.

6. Intended Purpose

SENTINA® AZURE NITRILE examination gloves are intended to be used for medical examinations and as protective gloves.

7. Classification

SENTINA® AZURE NITRILE examination gloves are a medical device of class I (according to MDR 2017/745).

SENTINA® AZURE NITRILE examination gloves are protective gloves of category III according to PPE regulation EU 2016/425.

8. Biological Evaluation and Biocompatibility (DIN EN ISO 10993)

The starting materials used in the manufacture of SENTINA® AZURE NITRILE examination gloves are safe if the product is used appropriately.

The purpose of this documentation and the statements made therein is to show that there is no unacceptable risk involved in the use of the medical device SENTINA® AZURE NITRILE examination gloves and that they are designed, manufactured and packaged in such a way that they will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

9. Requirements Regarding the Safety/Harmlessness of the Constituents

This product contains accelerators (dithiocarbamate) not to be used in a hypersensitivity of this substance.

10. Stability

Stored appropriately SENTINA® AZURE NITRILE examination gloves have a shelf life of 5 years.

The gloves must be protected from UV light and ozone. Storage at more than 30°C can speed up the ageing process and should therefore be avoided.

11. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse.

Packaging materials must also be disposed of in compliance with applicable national requirements.

12. Legal Manufacturer

The following legal manufacturer hereby confirms the accuracy of the information provided in this product data sheet:

Legal Manufacturer:

Anhui Intco Medical Products Co., Ltd.
Haitang Road West and Yinhua Road North
Suixi Wuhu Modern Industrial Park
Suixi Town, Huaibei City
Anhui Province
P.R. China

Distributor:

Lohmann & Rauscher International
GmbH & Co. KG
Westerwaldstraße 4
565679 Rengsdorf
Germany

2022.9.8. Fiona Qie
Date/Signature


Date/Signature

EC REP:

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