

Declaration of Compliance

We

Supplier Martin & Servera
 Box 1003
 121 23 Johanneshov, Sweden

Production unit Produced for Martin & Servera in China.

Declare on 2022-03-02 that

Product Nitrile Gloves
Are made of NBR



Item number	Description
353417	NITRILHANDSKE OP BL S EN100M/S
353805	NITRILHANDSKE OP BL M EN100M/S
355299	NITRILHANDSKE OP BL L EN100M/S
355404	NITRILHANDSKE OP BL XLEN100M/S
355432	NITRILHANDSKE OPUD SV S 100M/S
355477	NITRILHANDSKE OPUD SV M 100M/S
355608	NITRILHANDSKE OPUD SV L 100M/S
355644	NITRILHANDSKE OPUD SV XL100M/S

Has been produced according to

- REGULATION (EC) No 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
- REGULATION (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food (GMP).

Is compliant with

- REGULATION (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- REGULATION (EU) No 2016/425 on Personal Protective Equipment (PPE).
- BfR Recommendation XXI and XXI/1 on Commodities based on natural and synthetic rubber.
- REGULATION (EU) No 10/2011 on Plastic materials and articles intended to come into contact with food (referred to in BfR Recommendation XXI).
- DIRECTIVE 94/62/EC on Packaging and packaging waste.

Conformity assessment for PPE

Notified body:	SATRA technology, 2777
Risk category of product:	III
Assessment procedure:	Module B: EU type-examination according to annex V Module C2: Internal production control plus product checks at ransom intervals according to annex VII and Module D: Quality assurance of the production according to annex VIII
EU Type-examination:	Certificate number: 2777/14815-02/E00-00
Relevant harmonized standards:	EN 374-1:2016, 374-2:2015, EN 374-4:2019, EN 374-5:2016, EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 16523-1:2015, ISO 10993-10:2020.
Label:	CE-marking

Has been produced

From approved monomers:	Butadiene (CAS 106-99-0) and acrylonitrile (CAS 107-13-1) listed in (EC) No 10/2011, annex I, table 1.
With approved additives:	ZDBC/ZDEC and SDBS, listed in BfR Recommendation XXI/1, table 2.
Without the use of:	Plasticizers and azo colorants,

Does not emit

Limited substances above denoted levels in (EC) No 10/2011, annex II:

Monomers:	Test 2 (butadiene and acrylonitrile)
Metals:	Test 3
Primary aromatic amines:	Test 4
Formaldehyde:	Test 11
Nitrosamines:	Test 12 (nitrosamines and nitrosable substances)

Intended use

To types of food:	All kinds of food / All kinds of cold and hot liquid drinks.
Duration / Conditions:	Temporary handling of foods.

Test conditions used

For total migration

Duration:	0,5 and 2 hours, respectively
Temperature:	40 °C
Food-simulator:	3% acetic acid and 10% ethanol / olive oil, respectively (in accordance with BfR Recommendation XXI/1)
Ratio Contact area/volume:	10 dm ² /L food

For specific migration (of metals and formaldehyde)

Duration:	0,5 hours
Temperature:	40 °C
Food-simulator:	3% acetic acid (in accordance with (EC) No 10/2011, annex III, table 1)
Ratio Contact area/volume:	6 dm ² /L food (in accordance with (EC) No 10/2011, article 17)

For specific migration (of monomers)

Duration:	2 hours
Temperature:	100 °C
Food-simulator:	Water
Ratio Contact area/volume:	6 dm ² /L food (in accordance with (EC) No 10/2011, article 17)

Has passed relevant tests below

1.	Overall migration from rubber	According to BfR Recommendation XXI/1 on Commodities based on natural and synthetic rubber (category 3), section 4.1.
2.	Specific migration of butadiene and acrylonitrile	According to BfR Recommendation XXI on Commodities based on natural and synthetic rubber, table 1.
3.	Specific migration of metals from rubber	According to REGULATION (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
4.	Specific migration of primary aromatic amines from rubber	According to REGULATION (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
5.	Content of SVHC in rubber	According to REGULATION (EC) No 1907/2006 on REACH, Article 33(1) (as per update July 2021).
6.	Content of cadmium	According to REGULATION (EC) No 1907/2006 on REACH, annex XVII, entry 23.
7.	Content of lead	According to REGULATION (EC) No 1907/2006 on REACH, annex XVII, entry 63.
8.	Content of PAH	According to REGULATION (EC) No 1907/2006 on REACH, annex XVII, entry 50.
9.	Content of phthalates	According to REGULATION (EC) No 1907/2006 on REACH, annex XVII, entries 51 and 52.
10.	Content of zinc	According to BfR Recommendation XXI/1 on Commodities based on natural and synthetic rubber, section 4.2.
11.	Migration of formaldehyde	According to BfR Recommendation XXI/1 on Commodities based on natural and synthetic rubber, section 4.8.
12.	Migration of nitrosamines	According to BfR Recommendation XXI/1 on Commodities based on natural and synthetic rubber, section 4.5.
13.	Sensory analysis	According to DIM 10955.