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Test Report

Report No.:	**2100683 / 14674-E**	**Date:** 2021-07-15
Client:	Meditrade GmbH Medipark 1 83088 Kiefersfelden	
Supplier number:	79421	
Subject:	Examination gloves Nitril Next Gen, REF 1283M	
Task:	Testing according to ÖNORM EN 455-1 (2020), ÖNORM EN 455-2 (2015) & ÖNORM EN 455-3 (2015), ISO 2859-1 (1999) & ÖNORM EN ISO 21171 (2006)	
Order:	Order of 2021-06-24	
Date of sampling:	___	
Location of sampling:	No samples taken by OFI staff Samples provided by the client	
Receipt of samples:	2021-06-24	

Nicht akkreditierte Verfahren sind als solche gekennzeichnet.
Non-accredited procedures applied have been named as such.

1 SCOPE OF WORK

According to the order samples of examination gloves have been tested in accordance to ÖNORM EN 455-1 (2020), ÖNORM EN 455-2 (2015) and ÖNORM EN 455-3 (2015), ISO 2859-1 (1999) & ÖNORM EN ISO 21171 (2006).

2 SCOPE OF APPLICATION

The results given in this Test Report have been obtained under the specific conditions of the individual tests. They shall serve as proof for the client of the conformity of the samples tested to the requirements of the product standard(s) given.

Test Report has originally been drawn up in German. The German version shall be the authentic one and prevail over the English one for all matters of interpretation and construction. The English version shall only be deemed a translation for information purposes.

3 SAMPLE MATERIAL

Our client submitted the following samples for the purpose of testing:

- Examination gloves Nitril Next Gen, REF 1283M; size: M, Lot.no.:4020009430421, Prod. Date: 2021-04

Other documents submitted by our client:

No (other) documents submitted.

4 TESTS

Testing took place from 2021-07-01 to 2021-07-08.

The tests were carried out in the individual technical departments within the scope of competence of the authorised signatories according to the OFI QM manual.

4.1 Determination of leak tightness according to ÖNORM EN 455-1 (2020)

Testing was done according to the specifications of ÖNORM EN 455-1 using a testing device *"DOKA - HP"* (OFI device # 869). Applying a general inspection level I, for a lot size of 35001 to 150000 (L), and a double sampling plan for normal inspection with an AQL 1.5 (as listed in Table 3A of ISO 2859-1 (1999)), the sample size is 2 * 125 items, with a corresponding acceptance/rejection number of 3/6 for the first 125 items & a acceptance/rejection number of 9/10 for the second 125 items.

The number of sample items first inspected shall be equal to the first sample size given by the plan. If the number of nonconforming items found in the first sample is equal to or less than the first acceptance number, the lot shall be considered acceptable. If the number of nonconforming items found in the first sample is equal to or greater than the first rejection number, the lot shall be considered not acceptable.

If the number of nonconforming items found in the first sample is between the first acceptance and rejection numbers, a second sample of the same size given by the plan shall be inspected. The number of nonconforming items found in the first and second samples shall be accumulated. If the cumulative number of nonconforming items is equal to or less than the second acceptance number, the lot shall be considered acceptable. If the cumulative number of nonconforming items is equal to or greater than the second rejection number, the lot shall be considered not acceptable.

4.2 Determination of dimensions according to ÖNORM EN 455-2 (2015)

Testing was done according to the specifications of ÖNORM EN 455-2 using calibrated scales (OFI device #1015).

4.3 Determination of breaking force according to ÖNORM EN 455-2 (2015)

Testing was done according to the specifications of ÖNORM EN 455-2 using a universal testing machine “UPM Zwick Z100” (OFI device # 3.150) at a test speed of 500 mm/min and applying a pre-load of 0.1 N. The test climate was 23°C and 50% rH.

4.4 Determination of residual powder according to ÖNORM EN 455-3 (2015)[1] and EN ISO 21171 (2006)[1]

Testing was done according to EN 455-3 and the specification of ÖNORM EN ISO 21171 Method B. Determination was performed using 5 gloves.

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[1] Non-accredited procedures

5 RESULTS

5.1 Results of the leak tightness according to ÖNORM EN 455-1

Applying a general inspection level I, for a lot size of 35001 to 150000 (L), and a double sampling plan for normal inspection with an AQL 1.5 (as listed in Table 3A of ISO 2859-1 (1999)), the sample size is 2 * 125 items, with a corresponding acceptance/rejection number of 3/6 for the first 125 items & a acceptance/rejection number of 9/10 for the first and second 125 items. The results are shown in

Table **1**.

Table 1: Leak tightness of the tested gloves

Sample & Lot No.	Sample size	Acceptance / rejection number	Number of failures	Result
Nitril NextGen, REF 1283M; size: M, Lot.no.:4020009430421	125 items (first sample)	3/6 (for first sample)	1	Compliance
	125 items (second sample)	9/10 (for first sample + second sample)	N/A (Total = 1)	

*N/A: second sample was not measured due to determined failure number corresponding to acceptance/rejection number of first sample.

The tested gloves **meet** the requirements of ÖNORM EN 455-1 (leak tightness).

5.2 Results of the dimensions according to ÖNORM EN 455-2

The detailed results as well as the median values for the dimensions of the tested gloves are shown in

Table **2**.

Table 2: Physical dimensions of the tested gloves

Sample	Size	Requirements (ÖNORM EN 455-2)	Median value	Result
Nitril NextGen, REF 1283M; size: M, Lot.no.:4020009430421	M	Length: ≥ 240 mm	245	Compliance
		Width: 95 ± 10 mm	95	Compliance

The tested gloves **meet** the requirements of ÖNORM EN 455-2 (dimensions).

5.3 Results of the breaking force according to ÖNORM EN 455-2

The detailed results of breaking force of the tested gloves are shown in **Table 3**.

Table 3: Breaking force of the tested gloves

Sample	Breaking force [N] (Median value)	Requirements (ÖNORM EN 455-2)	Result
Nitril NextGen, REF 1283M; size: M, Lot.no.:4020009430421 (before ageing)	6.93	≥ 6.0	Compliance
Nitril NextGen, REF 1283M; size: M, Lot.no.:4020009430421 (after ageing)	7.10	≥6.0	Compliance

The tested gloves **meet** the requirements of ÖNORM EN 455-2 (breaking force).

5.4 Determination of residual powder according to ÖNORM EN 455-3 and ÖNORM EN ISO 21171

According to ÖNORM EN 455-3 the amount of residual powder must not exceed 2 mg/glove. The detailed results of the amount of residual powder determined by method B according to ÖNORM EN ISO 21171 are shown in Table 4. If the calculation results in a negative value for the residual powder, then the value is set to 0.00 mg/glove.

Table 4: Residual powder of the tested gloves

Sample	Residual powder [mg/glove]	Requirements (ÖNORM EN 455-3)	Result
Nitril NextGen, REF 1283M; size: M, Lot.no.:4020009430421	0.60	≤ 2 mg/glove	Compliance

The tested gloves **meet** the requirements of ÖNORM EN 455-3 (residual powder).

This Test Report No. **2100683 / 14674-E** comprises
7 sheets with 4 table(s), 0 figure(s) and 1 appendix(es).

Any test results relate only to the samples tested. Test Reports may be made available to third parties, either free of charge or against payment, if the full wording of the Test Report is given and if OFI is expressly named as the author. All tests applied are subject to a quality assurance program according to EN ISO/IEC 17025:2017.

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