TÜV Rheinland Nederland B.V.



TRN Report 89207518 Rev.01

Inspection report relating to walking aids according to the international standard ISO 11199-2, ISO 11199-3 and the EN 12182 concerning the rollator with trade mark: Schuchmann® type: Marcy and Malte

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- -

Project name

Type test rollator Marcy and Malte

Project number

89207518

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Abstract

The rollator, trademark: Schuchmann®, type: Marcy, version(s): Size 0, Size 1 and Size 2 and the rollator, trademark: Schuchmann®, type: Malte, version(s): Size 0, Size 1, Size 2, Size 3 and Size 4 have been tested according to the International standard ISO 11199-2 [1]. the International standard ISO 11199-3 [2] and the European standard EN 12182 [3].

The tests have been performed in order to judge whether or not the both type rollators meets the applied requirements of the above-mentioned standards.

The Marcy, version(s): Size 0, Size 1 and Size 2 and the Malte, version(s): Size 0, Size 1, Size 2, Size 3 and Size 4 are fully tested to the requirements of the International standard ISO 11199-2 ^[1]. After this test the Marcy, version(s): Size 0 and Size 2 and the Malte, version(s): Size 0 and Size 4 are tested as worst case to the requirements of the International standard ISO 11199-3 ^[2].

The conclusion is that the Marcy Size 0, Size 1 and Size 2 and the Malte Size 0, Size 1, Size 2, Size 3 and Size 4 shows compliance of the above mentioned requirements except for lever for folding mechanism.



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1 Introduction

1.1 Purpose

The tests have been performed in order to judge whether or not the products meet requirements of the International standard ISO 11199-2 [1], the International standard ISO 11199-3 [2] and the European standard EN 12182 [3].

1.2 Description of the sample(s)

| General | | | |
|--------------|-------------|--|--|
| Manufacturer | Schuchmann® | | |
| Trademark | Schuchmann | | |

Table 1: Description of the sample(s)

| Sample number Type | | Version | Serial number |
|--------------------|-----------------|---------|---------------------|
| MT15.39156.01 | Marcy | Size 0 | 2100110115-01/20002 |
| MT15.39156.02 | Marcy | Size 1 | 2100110115-02/20002 |
| MT15.39156.03 | Marcy | Size 2 | 2100110115-03/20002 |
| MT15.39156.04 | Malte | Size 1 | 2100030115-01/20002 |
| MT15.39156.05 | Malte | Size 2 | 2100030115-02/20002 |
| MT15.39156.06 | Malte (outdoor) | Size 3 | 2100070115-01/20002 |
| MT15.39156.07 | Malte | Size 3 | 2100030115-03/20002 |
| MT15.39156.08 | Malte | Size 4 | 2100030115-04/20002 |
| MT15.39156.09 | Malte | Size 3 | 737011410109 |
| MT15.39156.10 | Malte | Size 4 | Not labelled |



Picture 1: product label Marcy Size 0



Picture 2: product label Marcy Size 1



Picture 3: product label Marcy Size 2

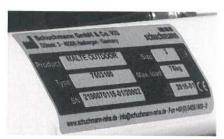




Picture 4: product label Malte Size 1



Picture 5: product label Malte Size 2



Picture 6: product label Malte Size 3 (outdoor)



Picture 7: product label Malte Size 3



Picture 8: product label Malte Size 4

For a more detailed description of the sample(s) is referred to Annex A.

The samples were delivered on 25 February, 2015.

The delivered samples were test worthy.

1.3 Sampling procedure

The samples have been submitted by the manufacturer.

The test house has had no influence on the selection of the samples.

1.4 Application

The request for testing was submitted by BEO Medconsulting Berlin GmbH, on January 28, 2015. Order number: 39156.

The request for partial re-testing was submitted by BEO Medconsulting Berlin GmbH, on September 7, 2015. Lead number: 76818.



1.5 Method of testing

All applicable tests have been performed according to the International standard ISO 11199-2 $^{[1]}$, the International standard ISO 11199-3 $^{[2]}$ and the European standard EN 12182 $^{[3]}$.



2 Test results

Test results after performing all applicable tests according to the standard ISO 11199-2 [1].

| Par. | Headline | Assessment (pass/Fail/N.a.) |
|---|--|-----------------------------|
| 4 | Requirements | |
| 4.1 | Manoeuvrability | Pass |
| 4.2 | Stability | Pass |
| 4.3 | Brakes | Pass |
| 4.4 | Handgrip | Pass |
| 4.5 | Leg section and tip | Pass |
| 4.6 | Resting seat | Pass |
| 4.7 | Mechanical durability | Pass |
| 4.8 | Adjusting devices | Pass |
| 4.9 | Folding mechanism | Pass |
| 4.10 | Adjustment and handles | Pass |
| 4.11 | Materials and finish | Pass |
| 6 | Information supplied by the manufacturer | Pass |
| For detailed results is referred to Appendix C. | | |

Test results after performing all applicable tests according to the standard ISO 11199-3 [2].

| Par. | Headline | Assessment (pass/Fail/N.a.) |
|------|-----------------------|------------------------------------|
| 4 | Requirements | |
| 4.1 | Stability | Pass |
| 4.2 | Brakes | Pass |
| 4.3 | Mechanical durability | Pass |
| 4.4 | Manoeuvrability | Pass |
| 4.5 | Handgrip | Pass |



| 4.6 | Leg section and tip | Pass |
|---|--|------|
| 4.7 | Adjusting devices | Pass |
| 4.8 | Resting seat | Pass |
| 4.9 | Materials and finish | Pass |
| 4.10 | Marking and labelling | Pass |
| 6 | Information supplied by the manufacturer | Pass |
| For detailed results is referred to Appendix C. | | |

Test results after performing all applicable tests according to the standard EN12182 [3].

| Par. | Headline | Assessment (pass/Fail/N.a.) |
|------|--|-----------------------------|
| 4 | General requirements | Pass |
| 5 | Materials | Pass |
| 6 | Emitted sound and vibration | Pass |
| 7 | Electromagnetic compatibility | n.a. |
| 8 | Electrical safety | n.a. |
| 9 | Overflow, spillage, leakage and ingress of liquids | Pass |
| 10 | Surface temperature | Pass |
| 11 | Sterility | n.a. |
| 12 | Safety of moving parts | Pass |
| 13 | Prevention of traps for parts of the human body | Pass |
| 14 | Folding and adjusting mechanisms | Pass |
| 15 | Carrying handles | Pass |
| 16 | Assistive products which support or suspend users | Pass |
| 17 | Potable and mobile assistive products | n.a. |
| 18 | Surface, corners, edges and protruding parts | Pass |



| 19 | Hand held assistive products | n.a. |
|----|---|---|
| 20 | Small parts | Pass |
| 21 | Stability | Pass |
| 22 | Forces in soft tissues of the human body | Pass |
| 23 | Ergonomic principles | Pass Except for lever for folding mechanism |
| 24 | Requirements for information supplied by the manufacturer | Pass |



3 Conclusion

The rollator, trademark Schuchmann, type Marcy, version: Size 0, Size 1 and Size 2 and the rollator, trademark: Schuchmann®, type: Malte, version(s): Size 0, Size 1, Size 2, Size 3 and Size 4, meets the requirements as stated in the International standard ISO 11199-2 [1], the International standard ISO 11199-3 [2] and the European standard EN 12182 [3] except for lever folding mechanism.

The test results exclusively relate to the inspected object.



4 References

- 1 International standard ISO 11199-2:2005, Walking aids manipulated by both arms - Requirements and test methods - Part 2: Rollators, (ISO 11199-2:2005, IDT), ISO, International Organization for Standardization, Geneva, Switzerland.
- 2 International standard ISO 11199-3:2005, Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables, ISO, International Organization for Standardization, Geneva, Switzerland.
- 3 European standard EN 12182:2012, Assistive products for persons with disability - General requirements and test methods. CEN/CENELEC, International Organization for Standardization, Brussels, Belgium.



5 Signature

| Author | Signature |
|-------------------------|--|
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| | 1/9/6// |
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| Expert medical products | |
| Approved by | Signature |
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