

Public Heath Institute Ostrava
Center of clinical laboratories
Workplace 1 - Ostrava
Laboratory for testing virucidal activity
Partyzánské nám.2633/7, Moravská Ostrava, 702 00 Ostrava
VAT: CZ71009396



TEST REPORT n. 8/2019/SVU

Quantitative carrier test for the evaluation of virucidal activity of instrument disinfection

Test method and requirements (phase 2/ step 2) according to EN 17111:2018

Customer: SCHULKE CZ s.r.o. Lidická 445 735 95 Bohumín

735 95 Bohumíı CZ Order number: Contract number: Reference number: not specified ZU/36718/2019

ZU/36804/2019

Identification of desinfectant - sample:

Product name:

Lot number:

Expiration:

Producer:

Storage conditions:

Diluent product recommended by the producer for use:

Product appearance:

The active substance(s) and its (their) concentration:

Purpose of product:

Date of delivery of the product:

Date of test:

CHIROSAN PLUS

105A190715

2021-07-15

SCHULKE CZ

-10 °C to 25 °C

drinking water

white powder

peracetic acid generated in situ

instrument disinfection in medical area

13.11.2019

27.11. - 23.5.2020

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Results - for details see annex:

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by hard water to 2% solution reduced virus titre $4,500 \pm 0,356$ lg after an exposure time 10 min and 15 min at temperature $20^{\circ}\text{C}\pm1^{\circ}\text{C}$, under clean conditions (0,3 g/l Bovine serum albumin), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Adenovirus type 5*, strain *Adenoid 75*, i.e. demonstrated virucidal activity to *Adenovirus* by more than 4 lg.*

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by hard water to 1% and 0,5% solution reduced virus titre $4,500 \pm 0,356 \, \text{lg}$ after an exposure time $\underline{15 \, \text{min}}$ at temperature 20°C±1°C, under clean conditions (0,3 g/l Bovine serum albumin), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Adenovirus type 5*, strain *Adenoid 75*, i.e. demonstrated virucidal activity to *Adenovirus* by more than 4 lg.*

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by hard water to 1%, 0,5% and 0,1% solution reduced virus titre 4,500 ± 0,356 lg_after an exposure time 30 min at temperature 20°C±1°C, under dirty conditions (3,0 g/l Bovine serum albumin + erythrocytes), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Adenovirus type 5, strain Adenoid 75*, i.e. demonstrated virucidal activity to *Adenovirus* by more than 4 lg.*

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by hard water to 2% solution reduced virus titre $5,000 \pm 0,000 \, \text{lg}$ after an exposure time $\underline{10}$ min and $\underline{15}$ min at temperature $20^{\circ}\text{C}\pm1^{\circ}\text{C}$, under clean conditions (0,3 g/l Bovine serum albumin), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Murine norovirus*, strain S99, i.e. demonstrated virucidal activity to *Norovirus* by more than 4 lg.*

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by hard water to 1% and 0,5% solution reduced virus titre $5,500 \pm 0,000 \, \text{lg}$ after an exposure time $15 \, \text{min}$ at temperature 20°C±1°C, under clean conditions (0,3 g/I Bovine serum albumin), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Murine norovirus*, *strain S99*, i.e. demonstrated virucidal activity to *Norovirus* by more than 4 lg.*

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by hard water to 1% and 0,5% solution reduced virus titre 5,000 ± 0,000 lg after an exposure time 30 min at temperature 20°C±1°C, under dirty conditions (3,0 g/l Bovine serum albumin + erythrocytes), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Murine norovirus*, strain 599, i.e. demonstrated virucidal activity to *Norovirus* by more than 4 lg.*

*The statement of compliance is based on a 95% coverage probability for the expanded uncertainty.

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Conclusion and interpretation:

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by water to **2**% solution **demonstrated virucidal activity** under the **clean conditions** after exposure time **10 min**.

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by water to **1%** solution **demonstrated virucidal activity** under the **clean conditions** after exposure time **15** min.

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by water to **0,5%** solution <u>demonstrated virucidal activity</u> under the <u>clean conditions</u> after exposure time **15 min**.

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by water to **1**% solution **demonstrated virucidal activity** under the **dirty conditions** after exposure time **30 min**.

According to EN 17111:2018 the test product **CHIROSAN PLUS**, lot.n. 105A190715, designed for instrument disinfection in medical area, diluted by water to **0,5%** solution <u>demonstrated virucidal activity</u> under the <u>dirty conditions</u> after <u>exposure time **30 min**</u>.

In Ostrava, 25.5.2020

Approved by: Mgr. Ludmila Porubová

Guarantor of testing

Zdravotní ústav se sídiem v Ústravě Centrum klinických laboratoří

Oddělení virologié
Partyzánské náměstí 2633/7
Moravská Ostrava 702 00 Ostrava
Telefon: 596 200 111, 310, 312

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