

<b>Trade name</b>	Sanifort effervescent tablets
<b>Indication</b>	CHLORINE TABLETS FOR GENERAL DISINFECTION AND DISINFECTION OF WATER
<b>Ref.-No..</b>	BPR TD040

<b>Standards, Documents, Number</b>	<b>Title</b>	<b>Issue Date</b>	<b>Verification / proof of evidence</b>
<b>Laws:</b>			
Regulation (EU) No 528/2012	Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.	22.05.2012	Entire Technical documentation
Regulation (EO) № 1272/2008	The CLP Regulation. European Regulation on classification, labelling and packaging of substances and mixtures	16.12.2008	Hazard classification (SDS)
<b>General standards</b>			
EN ISO 9001:2015	Quality management systems - Requirement	2015-09	Certified, documented quality system, see QMS documentation
<b>Packaging and Labeling</b>			
EN ISO 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices	2013-12	Chapter: Labeling and Packaging
EN ISO 15223-1	Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	2017-04	Chapter: Labeling and Packaging
<b>Standards for microbiological activity as per EN 14885</b>			
EN 1276	Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)		Report No166A/03.12.2004
EN14348:2005	Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – Test method and requirements (phase 2, step 1)		Report No158/13.12.2010

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EN14347:2005	Chemical disinfectants and antiseptics – Basic sporicidal activity - Test method and requirements (phase 1)	Report No144/21.10.2010
EN14476:2013	Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)	No 37 / 24.03.2011
EN 1650	Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas-Test method and requirements (phase 2, step 1)	Report No166A/03.12.2004
EN13697:2002	Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food and industrial, domestic and institutional areas – Test method and requirements without mechanical action(phase 2,step 2)	Report No15/08.04.2003
EN13624:2013	Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase2, step 1)	Report No16/11.12.2015
EN13727:2012	Quantitative suspension test for the evaluation of bactericidal activity for the medical area. Test method and requirements (Phase 2, Step 1).	Report No15/11.12.2015

## Approval

Reviewed and by	Zhivas Ltd
Date: 22.07.2019	Plamen Kamburov – Managing Director