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1. Report Identification

This document details the following information related to **NitrAdine® Disinfecting Tablets**

- General Information
- Regulatory and legal aspects
- Production
- Packaging
- Quality control
- References

2. General information

Article Nos.	23.900.00.M.0.0.00 NitrAdine® Denture Tabs 8.970.00.M.0.0.00 NitrAdine® Ortho & Junior 22.900.00.M.0.0.00 NitrAdine® Snoro Tablets / Bruxism Tablets 8.970.00.U.0.0.00 Lacer Orto proTabs 8.930.00.j.0.0.00 Yoshida Nitradine Denture Tabs and O&J combined 8.930.00.M.0.0.00 WHW Plastics Ltd MST Brand Denture Tabs and O&J combined
Product Name	NitrAdine® Disinfecting Tablets
Brand names	Denture Tabs, Ortho & Junior, Snoro Tabs, Bruxism Tabs, Lacer Orto proTabs, Yoshida Nitradine Denture Tabs and O&J, WHW Plastics Ltd MST Brand Denture Tabs and O&J.
Description	Patented disinfecting formula for removable dental appliances. NitrAdine® disinfecting tablet is intended to disinfect removable dental appliances such as dentures, orthodontic appliances, anti-snoring devices and anti-bruxism devices. This product is based on NitrAdine® formula which is known by its high in-vitro biofilm removal activity especially against *Candida albicans*, *Pseudomonas aeruginosa*, *Staphylococcus aureus, Enterococcus hirae* and viruses such as *Adenovirus, Poliovirus, Murine Norovirus.* The anti-biofilm activity was shown in several studies (See references under section 6). Triple action formula: 1. Penetrates the micro-porosities of the appliance. 2. Eliminates the micro-organisms. 3. Cleanses the appliance in depth. The disinfecting tablets work deep into the pores of the device without affecting the colouring or damaging its metallic parts.
Use, Toxicity & safety	NitrAdine® disinfecting tablets are for external use only. They may not be inhaled, applied directly into the mouth and should not be swallowed. Tablets should be kept out of reach of children. The tablet itself can be slightly irritating if it comes into direct contact with skin or eyes. If this occurs, rinse immediately with plenty of water and seek medical advice. Do not drink the solution. If the product is applied according to the instructions on the product packaging, there is no health risk by using NitrAdine® disinfecting tablets daily. Biocompatibility test report is available on request. The ingredients are listed and accepted for the use in the US and Europe.

Composition/Indication	

Ingredient Name	INCI Name	CAS No.
Citric Acid Anhydrous	Citric Acid	77-92-9
Texapon K 12 P	Sodium Lauryl Sulfate	151-21-3
Ludipress LCE	Lactose Monohydrate	5989-81-1
	PVP	9003-39-8
BICAR®FOOD	Sodium Bicarbonate	144-55-8
JuraSel® Speisesalz 100/40	Sodium Chloride	7647-14-5
Oxone(R) Monopersulfate compound PS-16	Potassium Monopersulfate	70693-62-8
Soda solvay ® light	Sodium Carbonate	497-19-8
Pfefferminz Aroma	Peppermint Flavour	n.a

Shelf life	3 Years

3. Regulatory & Legal aspects

Classification Europe	Medical Device Class IIb
Classification process	Classification according to Annex IX of Directive 93/42/EEC The product is classified as a medical device class IIb according to the Rule 15 of the annex IX of the Medical Device Directive 93/42/EEC. The MD Directive states: *"All devices intended specifically to be used for disinfecting, cleaning,rinsing or, when appropriate, hydrating contact lenses are in Class IIb.* *All devices intended specifically to be used for disinfecting medical devicesare in Class IIa.* ►***M5 Unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb***. ◄
NBOG-Code	MD 0108 Non-active medical devices for disinfecting, cleaning, rinsing
Target Audience	Denture, orthodontic appliances and anti-bruxism/anti-snoring appliances wearers.

4. Production

Hygiene	Hairnet Gloves Shoe covers Breathing mask Disinfectants Laboratory clothing Ref: SOP 165-Hygiene	
Components	Tablets covered with blister	
Machinery	Brand	Purpose
	Brunner	Box Packaging
	Sibler	Blistering
	Press Ronchi	Pressing tabs
	Press Tiwin	Pressing tabs

5. Packaging

Quantities	12, 20, 32, 64 tablet size boxes		
Material of blister paper of tablets	One Side Coated Paper + LDPE + Matt Aluminium foil + LDPE special N. The paper conforms to R.E.A.C.H. Directive 1907/2006 and complies with all the restrictions set out in the European Directives concerning packaging intended to come in direct contact with foodstuff.		
External packaging	Pre-printed cardboard.		
Instructions for use	1-page insert **Warning text (CLP)** Signal word Danger Causes skin irritation. Causes serious eye damage. Keep out of reach of children. Wash hands thoroughly after handling. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Contains Sodium lauryl sulfate; Pentapotassium bis(peroxymonosulphate) bis(sulphate). Contains Potassium persulfate and 2-Isopropyl-5-methylcyclohexanone. May produce an allergic reaction. **Precaution for use text** For external use only. Discard solution after use. Do not use if allergic to any of the ingredients or to persulfates. Do not put tablet in mouth. Tablet powder may cause eye damage. Do not drink the solution or use as a mouthwash. Rinse appliance well before replacing it in your mouth. Discontinue use and seek medical attention if any irritation, swelling or pain develops following the first or any later use. Consult instructions for use. Store in a dry place. For single use only.		
Symbols	Symbol	Standard/directive	Description

		EN ISO 15223-1:2016	Use by date Indicates the date after which the medical device is not to be used.
		EN ISO 15223-1:2016	Lot Number Indicates the manufacturer's batch code so that the batch or lot can be identified.
		EN ISO 15223-1:2016	CE MARKING OF CONFORMITY (93/42/EEC)
		EN ISO 15223-1:2016	Manufacturer
		EN ISO 15223-1:2016	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
		EN ISO 15223-1:2016	Consult instructions for use.
		EN ISO 15223-1:2016	Store in a dry place.
		EN ISO 15223-1:2016	For single use only.
	 Danger	CLP regulation	Signal word: Danger.

		Custom symbol	Do not drink.
		Custom symbol	Do not ingest.
		Custom symbol	Keep out of reach of children.
		Custom symbol	Rinse denture before use.* *Only used on Nitradine Denture Tabs box
Labelling	Different languages available		
Storage	Store in a dry place.		
Delivery	6 Weeks after initial order		

6. Quality control

Properties	Specification	Method
Appearance Colour Odour	Solid tablet White Peppermint flavour	NA NA NA
Net Weight	2,30 – 2,60 g	Balance SOP-48
Hardness	≥ 30 N	Hardness Tester Schleuniger SOP-48
pH	3,60 bis 4,30	in 150 ml aqua at RT SOP-48
Water	≤ 6 %	Titrino, Sartorius SOP-48
Solubility	≤ 5 Minutes	in 150 ml H2O at (30-35) °C SOP-48
Blister Integrity	meets Spec.	Exsiccator with H2O SOP-48
Temperature Stability	65 °C	Incubator for 24 hours SOP-48

7. References

Additional Technical Information	Material Safety Data Sheet Product Description Declaration of Conformity Biocompatibility report: Sterlab (France) Safety assessment Report: Intertek (UK)
Scientific References	- Biofilm activity of Nitradine tablets. Tom Coenye. Report bonyf 2018-1: GENT, Belgium, 2018. - Use of the modified Robbins device to study the in vitro biofilm removal efficacy of NitrAdineTM , a novel disinfecting formula for the maintenance of oral medical devices. Coeyne,T. et al., J Appl. Microbiology, 2008 - Evaluation of the sanitization effectiveness of a denture cleaning product on dentures contaminated with known microbial flora. Glass, Bullard, Conrad, Blewett, Quintessence International, 35,3, 194-199, 2004. - Reassessing the presence of candida albicans in denture related stomatitis. Barbeau J, Oral Seguin J., Goulet JP, de Koninck L, Avon SL, Lalonde B, Rompre P, Deslauriers N. Surg Oral Med Oral Pathol Oral Radiol Endod. 95:51-59, 2003. - Adhesion of oral candida albicans isolates to denture acrylic, following limited exposure to antifungal agents. Ellepola AN, Samaranayake LP. Arch Oral Biol. 43: 999-1007, 1998. - Oral fungal infections. Muzyka BC. Dent Clin North Am. 49(1): 49-65, 2005. Colonization and penetration of denture softlining materials by candida albicans. Balud K, Taylor RL, Verran J, McCord JF. Dental Materials, 20: 167-175, 2004. - The aetiology, diagnosis and management of denture stomatitis. Wilson J. Britisch Dental Journal 185 (8): 380-384, 1998. - Microbiological hazard analysis in dental technology laboratories. Verran J, McCord JF, Maryan C, Taylor RL. Eur. J. Prosthodont Restor Dent, 12 (3): 115-120, 2004.
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Advertising	Samples on request

8. Report control

8.1 Revision History

Change-No.	Rev-No.	Change Description	Author	Date
NA	10	Update	AS	28/10/2014
NA	11	New template + Add warning text (CLP) + Quality control+ Reference to instructions	IH	11/11/2015
NA	12	Updated article number info, updated product description updated symbols, made new point for packaging, moved history table to end of document, deleted table of contents	LS/BJ	06/09/2016
NA	13	Update according to the new classification, classification rule, add snoro and bruxism tabs, add new CLP text	IH	03/12/2018
NA	14	Update according to the new classification rule applied for devices used for disinfecting invasive devices- change of the intended use - update of SOP reference in quality control section – add NB number to CE symbol.	AS	19/06/2019
NA	15	The document is updated with reference to the comments of DEKRA in the examination report No. 50537-T4-00.	AS	20.09.2019

8.2 Report Release

This Document need to be verified by a second person and released by the Process owner or Quality Department.

Role	Name	Department	Signature and Date
Author	Dr. Amina Sakly	Regulatory/Clinical Affairs	Sakly Amina 2020.05.26 08:30:51 +01'00'
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