TECHNICAL DOSSIER	NEX IODIO P2 7,5% *surgical brush-sponge*

Date: January 2017
Rev.: 05

MANUFACTURER:
NEX MEDICAL ANTISEPTICS SRL
20010 CASOREZZO (MI) - ITALY
www.nexmedical.com; info@nexmedical.com

NEX IODIO P2 PVP-I 7,5%

SURGICAL SCRUB BRUSH/SPONGE

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1. ITEM CODE

Product name: NEX IODIO P2 PVP-I 7,5% surgical BRUSH-SPONGE

Product Ref.: **P2 PVP-I 7,5%**

2. FORMULATION

100 g. of product contain:
Povidone Iodine g. 7,5 (*)
made up to g. 100 with excipients and water

INGREDIENTS	Quantity	CAS number
Active ingredient(s)		
Polyvinyl Pyrrolidone iodine at 10%	g. 7,5	25655-41-8
Excipients and purified water up to	g. 100,00	

(*) Active Iodine 0,75g

3. CHEMICAL AND PHYSICAL PROPERTIES

Parameter	U.o.m.	Standard values
Aspect	--	Dark brown solution
Odour	--	Characteristic of iodine
Density	g/ml at 20°C	1,025-1,045
PH	U of PH a 20°C	4,5-6,0

4. PRODUCT DESCRIPTION

NEX IODIO P2 7,5% is a single use surgical brush-sponge impregnated with approx. 20ml of Povidone Iodine antiseptic solution.

5. USE

Surgical hand scrub for cleansing hands and arms prior to surgery.

6. BACTERICIDAL ACTIVITY

Direct action towards Gram+ and Gram- bacteria.
Microbiological tests validation according to the following European Standards:

- **EN 1040/1997: Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics (test methods and requirements - phase 1)**
  This European Standard specifies a suspension test for establishing whether a chemical disinfectant or antiseptic does or does not have a basic bactericidal activity in the field described in the scope.

- **prEN 12054/1995/EN 13727: Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of the bactericidal activity of products for hygienic and surgical handrub and handwash used in human medicine - test method and requirements - (phase 2, step 1)**
  This European Standard describes a suspension test for establishing whether a handrub or handwash product used for postcontamination treatment of hands or for surgical hand disinfection has or does not have bactericidal activity under laboratory conditions defined by this Standard.

- **EN 12791/2013: Chemical disinfectants and antiseptics - Surgical hand disinfection(*) - Test method and requirements (phase 2, step 2)**
  This European Standard specifies a test method simulating pratical conditions for establishing whether a product for surgical hand disinfection reduces the release of hand flora according to requirements described in clause 4 when used for the disinfection of the clean hands of volunteers.

- **EN 1650:2008: Chemical disinfectants and antiseptics**
  Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics (phase 2, step 1): ATCC 10231 *Candida Albicans.*

- **EN 13727: Chemical disinfectants and antiseptics**
  Quantitative suspension test for the evaluation of bactericidal activity in the medical area (phase 2, step 1).

(*) Surgical hand disinfection: preoperative treatment procedure that involves applying a bactericidal product directed against the bacterial flora of hands to prevent the risk of transmission of bacteria into the surgical wound.

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7. DIRECTIONS

Wet hands and forearms with water. Clean under nails with nailcleaner. Scrub for at least 3 minutes paying particular attention to nails, cuticles and interdigital spaces. Rinse and repeat scrub. Discard brush-sponge. Rinse hands and forearms thoroughly and dry with sterile cloth.

8. DERMAL TOXICITY

Dermal irritation and skin sensitization tests according to OEDC Guidelines N°404 and N°410 and ISO 10993.
No signs of dermal irritation and/or sensitization have been detected.

9. WARNINGS

For external use only.
Irritating to eyes.
Keep out of reach of children.
Avoid contact with eyes and ears. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
If swallowed, seek medical advice immediately and show the label.

10. EXPIRY DATE

24 Months.

11. PACKAGING

Primary pack:

Flexible blister pack unit with easy peel-off system
Materials: PE medical grade films
Variable data: MAN; EXP; LOT;

Secondary pack:

Display box-dispenser 40 units
Materials: cardboard
Features: Front easy opening; Inspection window; Eurohole flap for wall mounting
Variable data: MAN; EXP; LOT;

Master carton:

Corrugated outercase for 6 box-dispensers
Variable data: MAN; EXP; LOT (on label)

Packaging configurations

Primary pack	Secondary pack	Master carton	Pallet
Blister pack single unit	40 units/Box-dispenser	240 units/carton (6 box-dispensers X 40 units)	24 cartons (5.760 units)
Blister pack single unit	25 units/Box-dispenser	225units/carton (9 box-dispensers X 25 units)	24 cartons (5.400 units)
Blister pack single unit	--	100 units/carton	48 cartons (4.800 units)
Blister pack single unit	--	240 units/carton	24 cartons (5.760 units)

All materials are LATEX free.

12. MANUFACTURER

NEX MEDICAL ANTISEPTICS S.R.L.
Via per Arluno, 37/39 - 20010 Casorezzo (MI) - ITALY
Reg. # 20/2008/Off.280 issued by the Italian Ministry of Health
Reg. FDA DUNS # 43-356-4874

NEX MEDICAL plant is certified ISO 9001:2008 and ISO 13485:2012