

**Product Description**

**Intended Purpose**

MEDICAL DEVICE - Huwa-San 7,9 MD is a ready-to-use disinfectant for non-invasive medical devices and equipment (under clean conditions) by nebulization with a compatible nebulizer distributed by Roam Technology. Not intended to be used on patients.

A compatible nebulizer fulfills the next requirements:

- Minimum flow rate of 30 ml/min;
- VMD (Volume Median Diameter), the droplet size where the half of the volume of the spray is in droplets smaller, and half of the volume in droplets is larger, should be max 40µm;
- Nozzle based on Venturi effect

Can only be used on compatible non-invasive medical devices. Incompatible materials are Chromium (Cr), Copper (Cu), Iron (Fe), Nickel (Ni), Manganese (Mn), Zinc (Zn). See MSDS. Disinfection is done by chemical oxidation of cellular component, resulting in rapid microbial death.

Efficacy can only be guaranteed when the medical device is used with a compatible nebulizer, distributed by Roam Technology. Make sure the surfaces are cleaned with water prior to disinfection. In case a detergent is used, please rinse with clear water. Allow 60 minutes contact time after nebulization. Nebulization must be done in an enclosed space.

Efficacy: Bactericidal (EN13727), fungicidal (EN13624), virucidal (EN14476), mycobactericidal (EN14348), sporicidal (EN17126). Tests performed at 20°C.

By disinfecting the non-invasive medical devices, infections of patients and environment are prevented. Huwa-San 7,9 MD is intended for single use because effective disinfection cannot be guaranteed during reuse, and ineffective disinfection may lead to risk of infection for the patient. The user must observe the directions for use, as non-compliance may affect the safety and health of the product.

**Intended User and Use Environment**

Use of Huwa-San 7,9 MD is restricted to professional users and persons trained in the decontamination and disinfection of medical devices, and the handling of liquid chemical disinfectant. Can only be used in a healthcare environment.

**Indications**

Huwa-San 7,9 MD is not intended to be used on patients. It is a risk control measure for reducing the risk of infections.














**Contra-indications**

Huwa-San 7,9 MD should not be used outside a healthcare setting.

**Composition**

Hydrogen Peroxide (CAS 7722-84-1): 7,9%wt

**General Marks and Symbols**

-  Medical Device, labelling of medical devices
-  Store in upright position
-  Storage temperature: between +5°C and +30°C
-  Keep away from sunlight
-  Keep dry
-  Do not use if package is damaged
-  Batch Code
-  Date of manufacture, expressed as YYYY-MM-DD
-  Use-by date, expressed as YYYY-MM-DD
-  Manufacturer
-  Consult instructions for use
-  Reference Number (Article Number)
-  CE-mark for medical devices (1639 = Notified Body Number)



Do not re-use (Single use product)



Caution: Please note accompanying documents

**Transport and Storage**

Huwa-San 7,9 MD should be stored in its original packaging at a temperature between 5° C and 30° C. Keep away from sunlight. Keep dry and store in upright position. If stored under the appropriate conditions, the products has a shelf-life of two years. Keep bottle closed until use.

**Safe Disposal**

Disinfectant: Check local regulations. The liquid has corrosive and oxidizing properties. Disposal of Huwa-San 7,9 MD is generally allowed by discharging the solution into drain after the dilution with water, because it decomposes into water and oxygen.

Container: Do not reuse empty container. Rinse and dispose per local policy

**Warnings**



Before using the product, read thoroughly the safety data sheet. This can be obtained through the local distributor or by sending a mail to info@roamtechnology.com.

Causes serious eye irritation.

**Precautions**



Wear safety gloves/eye protection when working with the medical device. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice.

In case of accidental ingestion, do not induce vomiting, seek medical advice immediately and contact Poison Control Centre.

Contact with Huwa-San 7,9 MD may discolor skin. Wipe up immediately if spilled.

Wash hands thoroughly after handling.

Do not use product if the packaging is damaged, unintentionally opened before use or if the packaging is exposed to environmental conditions outside of those specified.

The instructions for use are a component of the product and must be read carefully prior to use and must be accessible at all times. The medical device may only be used in accordance with the intended use, any other type of use is not permitted

UFI: RU52-YOTM-J002-DQG1

**NOTE**

All serious events occurring in relation to the medical device must be reported to the manufacturer and the competent authority of the Member State, in which the user and/or patient resides.