CLINICAL VALIDATION

Piston Nebulizers

1.- INTRODUCTION

Piston aerosols and PiC accessory kits are devices indicated in the treatment of oral and respiratory affections (aerosol therapy). The therapy consists of aspirating, by mouth and / or nasal, a liquid medicament suitably sprayed into very small particles in air suspension. This therapy is therefore indicated in the treatment of oral and respiratory diseases.
They are therefore suitable instruments for the oral administration by nebulization of the most common drugs for the treatment of the upper and lower respiratory tract in an extremely effective and rapid manner. The medicated liquid, previously poured into the nebulizing chamber, is nebulized in particles with a suitable diameter and aspirated by the patient so as to act at the level of the upper and lower respiratory tract, in an extramonic manner. Quite silent and fast, favoring the hydration and the fluidification of the mucus and the phlegm. It is suitable for patients of all ages, but particularly useful in children.
For this purpose, Piston appliance and accessories for aerosol therapy are produced.
This document describes the company activities in compliance with art.15, all. X, of Dir. 2007/47 / CE concerning Medical Devices.
The device consists of a motor that controls a fan that guarantees air flow and a kit of accessories contained in a special plastic container.
During the design of the appliance, all the risks related to its use were taken into account and after their identification, their subsequent reduction to an acceptable level or total elimination was carried out

2.- STANDARD

2.1.- Reference standards

UNI EN 13544-1: 2009 - Respiratory therapy equipment - Part 1: Nebulizing systems and their components (EN 13544-1: 2007 + A1: 2009)
The aerosols and accessory kit with CE0068 PIKDARE S.r.l. are manufactured in compliance with the aforementioned regulation.
Compliance with the standard is verified through the checks carried out on each production batch.
The type of equipment and the operating principle are widely known and disseminated on the market and at the bibliographic level

2.2.- Compatibility with the accessories

Piston aerosols PIKDARE S.r.l. are used in combination with accessories, which
are mechanically connected.
The geometric compatibility between compressor and accessory kit is verified through the checks carried out on each production batch.
The absence of complaints, incidents and complaints recorded through follow-up investigations from the market, help to confirm that the dimensions are suitable for the intended use

2.3.- Suitability of the product

Piston aerosols and accessories by PIKDARE S.r.l. bearing the CE0068 marking in accordance with the Community Directive no. 93/42 / CEE (Implemented with D.L. n. 46 of 24/02/1997) and amended by Dir. N. 2007/47 / CE of 05/09/2007 (implemented with Legislative Decree No. 37 of 25/01/2010) under the responsibility of the Manufacturer PIKDARE S.r.l., are subject in addition to the final checks before their marketing to the following checks:

- electrical safety
- noise
- performance
- aesthetic / visual
- manual check and labeling

The checks are performed in accordance with internal procedures.

The follow-up complaints from the market are constantly monitored in order to ensure that the products are suitable for their intended use .

2.4. Pckaging

Piston aerosols and PiC accessory kits from PIKDARE S.r.l. bearing the CE0068 marking in accordance with the Community Directive no. 93/42 / CEE (Implemented with D.L. n. 46 of 24/02/1997) and amended by Dir. N. 2007/47 / CE dated 05/09/2007 (implemented with DL No. 37 dated 25/01/2010) under the responsibility of the Manufacturer PIKDARE Srl, are individually packaged and packaged.

The characteristics of both packaging guarantee the product adequate protection for its useful life, from the electrical and mechanical point.

The stability studies show that the packaging is IDEAL for the intended use

2.5. Label

The aerosol devices indelibly show the following symbols:

-CE with notified body number 0068
- type of part applied
- Electric protection class
- Manufacturer identification data
- Device identification data (model, code, lot number and / or serial number)
- Symbols required by law
- RAEE symbol

he packs of the accessory kits show the following symbols identifiably:

- CE with notified body number 0068
- Manufacturer identification data
- Identification data of the device (code, lot number and / or serial number)
- Symbols required by law
- RAEE symbol

Please refer to the individual technical files for the detailed content of the product markings.

The control of the labeling of the products placed on the market is carried out during the final control process according to internal procedures.

The compliance of each label with the regulatory requirements and the absence of complaints regarding the information affixed to the labeling shows that the labeling is COMPLIANT

3.- SECONDARY EFFECTS, BIOLOGICAL COMPATIBILITY

The biocompatibility tests carried out in compliance with the requirements of the EN ISO 10993-1: 2009 + AC: 2010 standard (ISO 10993-1: 2009) have shown that the parts of the device in contact with the patient are biocompatible.
During the years of marketing of the same type of products have never been complaints / reports related to lack of biocompatibility of the product

4.- TREATMENT OF RESPIRATORY DISEASES

The benefits and suitability for use with children of ultrasonic aerosol produced and marketed by us are indicated in the bibliographic documentation of which, following paragraphs 4.1, 4.2 and 4.3, an extract.

4.1- PEDIATRIC PNEUMOLOGY - AEROSOLTERAPY OF LOW AIRWAYS: the pathophysiological conditions

(Abstract)

Source: Pediatric Pneumology 2003- Elisa Milanesi, Ilaria Romei, Giorgio Piacentini Pediatric Clinic - University of Verona (see part C All.C8 Bibliography)

The aerosol therapy appears today as the best approach in the treatment of diseases of the lower respiratory tract, as the inhalation route is the most rational way for the administration of drugs, allowing the drug to be delivered directly into the target organ, without having to carry out the passage in the blood stream, in order to achieve the same effect at a lower dosage than that required by an oral or parenteral therapy.

4.2- THE TARGETED INALATORY THERAPY (Abstract)

(Source: Journal of Immunology and Pediatric Allergy) 01/2014 • 32-37, Amelia Licari, Silvia Caimmi, Maria Chiara Leoni, Enrica Manca, Marta Brambilla, Daniela Guardo, Gian Luigi Marseglia, Pediatric Clinic, University of Pavia, Department of Clinical-Surgical, Diagnostic and Pediatric Sciences, IRCCS Policlinico San Matteo Foundation, Pavia gl.marseglia@smatteo.pv.it.)

Inhalation therapy is one of the oldest therapeutic approaches for treating airway diseases, as it allows the drug used to act directly on the target organ, avoiding the use of systemic administration and offering the opportunity to obtain the same effect with a lower dosage than that required by oral or parenteral therapy. Its therapeutic efficacy depends on a number of factors including the correct diagnosis, the choice of drugs, the efficiency of the device and the methods of inhalation.

Benefits of inhalation therapy and principles of aerosol therapy

The inhalation route is the most effective route of administration in distributing the drug in the airways, both intra and extra-pulmonary. Inhaled drugs are commonly referred to as aerosols.

Therapeutic indications of aerosol therapy in children

Inhalation therapy is indicated in all those diseases that, at any age, have clinical pictures characterized by obstruction of the upper and lower airways and wheezing. The most significant clinical pictures in pediatric age are:

• High airways: rhinitis, sinusitis, laryngitis, tracheitis;

• Low airways: bronchodysplasia or chronic pneumopathy of the premature, bronchitis, bronchiolitis, bronchopneumonia, recurrent bronchospasm during infections, especially viral, and bronchial asthma. In the small child, for the problems related to crying, the variability of respiratory parameters and the inability to coordinate respiratory acts, nebulizers are used**.**

4.3- AEROSOLTERAPY (Abstract)

(Source Italian Journal of Genetics and Pediatric Immunology - Italian Journal of Genetic and Pediatric Immunology - Year III number 2 - April 2011; Laura Lo Valvo, Tiziana Timpanaro, Papale Maria (Department of Pediatrics, University of Catania)

Using aerosol it is possible to administer numerous drugs such as β2 agonists, steroids, anticholinergics, chromones, antibiotics, ribavirin, rhDNASE and vaccines.

Among the respiratory pathologies, asthma plays a role of primary importance being one of the major causes of morbidity and mortality in the world. Furthermore, there is evidence that its prevalence has increased significantly over the last 20 years, especially in children. For these reasons, aerosol therapy finds its main field of action precisely in this condition. There are three main devices for performing aerosol therapy: nebulizers, pressurized inhalers (MDIs) and dry powder inhalers (PDIs); many models are available of each type.

NEBULIZERS

We distinguish two types of nebulizers: pneumatic and ultrasonic.

The pneumatic nebulizers exploit the Venturi effect, as the liquid to be sprayed is pushed by a compressed gas towards a narrow orifice (Venturi).

In ultrasonic nebulizers, nebulization occurs thanks to high frequency sound waves that propagate in water and break up the solution, transforming it into thin fog.

INDICATIONS

The use of nebulisers is indicated in children under the age of one year, in all ages where there is poor collaboration and finally, in all those patients who are unable or unable to use other devices due to their incapacity. They are also useful in cases where it is necessary to administer high doses of the drug.

Nebulizers can be used at any age without any difficulty because they do not require a respiratory procedure other than physiological and even the sick child can easily use them. They can be used to administer high doses and do not contain propellants.

5.- CONCLUSIONS

Responding to the aspects of functionality previously described by the EN 13544-1 Standard, considering the results of the biocompatibility tests, validation data collected in the clinical field, the absence of reports from the market (post market clinical follow up), including the monitoring of the health ministry site, also considering the bibliographic publications attached to the Technical File in part C C.8 ("AEROSOLTERAPIA", "Pneumologia_pediatrica", "Aerosol_e_Aerosolterapia").

On the basis of the above, the accessory kits for ultrasonic aerosol devices and the Air Projet PiC ultrasonic aerosol devices of Pikdare S.r.l. they are considered COMPLIES WITH the requirements of the Community Directive No. 93/42 / EEC (Implemented with DL No. 46 of 24/02/1997) and amended by Dir. 2007/47 / EC of 05/09/2007 (implemented with DL n 37 dated 25/01/2010) and SUITABLE for the use for which they are intended.

Casnate con Bernate, 24/06/2019

Cassani Dr. Mauro