Presse release
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New approach to reducing allergic rhinitis symptoms:

M. Richard Laboratories obtains CE marking for its ionic nasal solution

M. Richard Laboratories announced today that it has obtained CE marking under Regulation (EU) 2017/745 on medical devices (MDR – Medical Devices Regulation) for its ADW S-100® nasal spray, an ionic solution based on Advanced Water S-100® for cleaning the ENT area.
This 100% natural solution offers a non-medicinal alternative for patients over 18 years of age, aimed at reducing the symptoms (runny nose and sneezing) caused by allergic rhinitis.

This multifactorial condition can sometimes be particularly debilitating for patients and currently affects a quarter of the French population and up to 80% of people with asthma[1,2]. The prevalence of allergic rhinitis has increased fourfold in thirty years, and the WHO estimates that it could affect 50% of the global population by 2050.

The CE marking, a certificate of compliance with strict European requirements in terms of safety and performance

European certification recognises the compliance of the 20 ml mechanical nasal spray, a Class IIa medical device, with European Union standards and requirements for patient safety, quality, traceability, clinical performance and risk management. The CE marking is awarded following a rigorous, impartial and thorough evaluation process conducted by the European Medical Certification Group (GMED). This body, officially designated by the French authorities and the European Commission to certify medical devices before they are placed on the European market, based its decision on pre-clinical and clinical studies that demonstrated the safety, biocompatibility in humans and efficacy of the device developed by M. Richard Laboratories.

"We are particularly proud to have obtained CE marking under MDR regulations for our ADW S-100® ionised water-based nasal spray. This is very good news for patients suffering from allergic rhinitis and for M. Richard Laboratories, which today reaffirms its strong ambition in the field of health with a significant French footprint. Thanks to this recognition, we hope to launch and market the product in France and Europe as early as 2026." **Mohamed MOSTEFA SIDE LARBI (PhD), Director of Development at M. Richard Laboratories.**

An essential step in bringing this 100% natural and biocompatible nasal spray to the European market, obtaining CE marking also paves the way for broader access to the international market by simplifying local registration procedures in many countries outside the European Union. It enables M. Richard Laboratories to assert a decisive role in the

[1] https://cep.splf.fr/wp-content/uploads/2023/07/ITEM_188_ASTHME_RHINITE_2023.pdf
[2] Charpin D, Caillaud D. Epidemiology of pollen allergy. Rev Mal Respir 2014;31(4):365–74.

medical device sector for the treatment of allergic rhinitis symptoms. It demonstrates their commitment to developing medical devices that are safe and respectful of users' health, and helps to strengthen the confidence of healthcare professionals, distributors and patients alike.

As part of their subcontracting activities[3], M. Richard Laboratories will begin production of the spray in January 2026 at their site in Saulce-sur-Rhône, near Montélimar, in a 7,500 m² facility dedicated to pharmaceutical products, medical devices and food supplements.

A mechanism of action and scientifically proven efficacy in the management of two symptoms of allergic rhinitis

The nose is the first line of defence against allergens, dust, pollutants and micro-organisms. The result of several years of research, ADW S-100® nasal spray from M. Richard Laboratories is based on Advanced Water S-100®, an innovative, stable alkaline water charged with ions (OH-). This patented technological innovation, already used in dermatology, was obtained through an electrolytic process.

This is the first time it has been used in a nasal spray for cleaning the ENT area. M. Richard Laboratories has just obtained CE marking for this innovation, paving the way for a new approach to reducing the symptoms of allergic rhinitis with a non-medicinal solution.

Scientific tests conducted by the laboratory have demonstrated the benefits of this ionic solution on two symptoms caused by allergic rhinitis, notably reducing rhinorrhoea by 41.7%[4]. Pre-clinical and clinical studies have proven that, thanks to its mechanical action, regular use of ADW S-100® nasal spray helps eliminate impurities in the nasal passages (allergens, dust and micro-organisms) and mucus. The in vitro pre-clinical study conducted by Epithelix demonstrated stimulation of mucin secretion (thereby reducing mucus viscosity) and improved ciliary beat (increased frequency of nasal cilia beating)[5]. Furthermore, the clinical study showed that, when administered as a nasal spray, this solution reduces the allergic reaction (-37.5% sneezing) and soothes irritated mucous membranes (reducing itching in 40% of patients, watery eyes in 1 in 2 patients and redness in nearly 59% of patients)[4].

Moreover, comprehensive testing of biocompatibility and tissue integrity has demonstrated the safety of ADW S-100® nasal spray and the absence of significant toxicological risk under normal conditions of use in adults over 18 years of age, after 3 sprays in each nostril 3 times a day (or 4 times a day if necessary) over a period of up to 3 months. These results were confirmed by the results of irritation (ISO 10993-10) and cytotoxicity (ISO 10993-5) tests.

Following the award of CE marking, medical monitoring will be put in place to collect “real-life” data as part of a post-marketing study involving users of ADW S-100® nasal spray. The aim is to reinforce the product's long-term viability.

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[3] Subcontractor activity under GMP Pharma and ISO 13485 certification.
[4] Results obtained after 14 days of use in the SPRA clinical study, a randomised, double-blind, placebo-controlled trial conducted on a panel of 96 users, 10 October 2023.
[5] Epithelix pre-clinical study using a human nasal epithelial cell model with high trans-epithelial electrical resistance, cilia beating and mucus production similar to epithelial tissue. Study conducted on MucilAirTM Pool nasal epithelium model, 11 October 2024.

Encouraging properties and results for future expansion into new indications

In France, nearly a quarter of the population is affected by allergic rhinitis, and its prevalence has continued to increase in recent years due to multiple factors related to genetics, the microbial environment, smoking and air pollution[1,2]. Faced with this public health challenge and buoyed by encouraging results in reducing two of the symptoms of allergic rhinitis, M. Richard Laboratories will submit an application for certification for a 50 ml and 100 ml aerosol version of BOV. The idea behind this new format is to better meet the needs of patients suffering from more persistent or chronic symptoms.

ADW S-100® nasal spray is indicated for adults over 18 years of age who may benefit from nasal cleansing and who suffer from symptoms of rhinorrhea and/or sneezing that may be caused by allergic rhinitis. Further studies are planned to extend the indication to patients under 18 years of age. In addition, a new clinical study will be conducted in the near future (2026-2027) to extend the current indication to other conditions such as the common cold and other seasonal viruses.

In addition to improving respiratory comfort and quality of life for patients with allergic rhinitis, the ionised water used in M. Richard Laboratories ADW S-100® nasal spray is also used in dermatology. Recognised for many years, particularly in Japan and Korea, it is used for its cleansing, soothing and protective properties to treat numerous skin conditions and as a therapeutic support in the management of various pathologies.

About M. Richard Laboratories

M. Richard Laboratories is a French pharmaceutical company based in Saulce-sur-Rhône, in the Drôme department (26). Acquired in June 2017 by P&B Group, the company has been part of P&B Group's Health Division since 2018, integrated into the group's diversification strategy. It positions itself as a site specialising in the production of pharmaceutical products, medical devices and food supplements, developing innovative formulas in particular.
Located near Montélimar, M. Richard Laboratories specialises in the manufacture and packaging of these same products. Their 7,500 m² site brings together technologies dedicated to dry, liquid and paste forms, as well as a wide range of packaging: sachets, sticks, pots/pill boxes, bottles, blister packs, tubes, aerosol cans with nitrogen-filled pouches.
Certified to pharmaceutical GMP, ISO13485 and HACCP standards and equipped with a comprehensive physical and chemical testing laboratory (HPLC, CPG, spectrophotometry, among others), they ensure consistent quality from raw materials to finished products. With production capacities of up to tens of millions of units per year, they support their partners in industrial projects ranging from small to large production runs.
For more information : https://labomrichard.com/