



## Press Release

# Resyca receives Medical Device Regulation Certificate from TÜV SÜD

*MDR Certification Strengthens Resyca's Leadership in Soft Mist Drug-Device Combination Products*

**Enschede, Netherlands, January 28, 2025** – Resyca BV, a pioneering leader in the development and manufacturing of advanced inhalation drug delivery devices, proudly announces successful certification under the European Medical Device Regulation (MDR, Regulation (EU) 2017/745) by notified body TÜV SÜD Product Service. This certification marks a significant milestone, demonstrating that all Resyca's design, development, and manufacturing processes comply fully with stringent MDR requirements.

With MDR certification, Resyca is strategically positioned to support its pharmaceutical partners in navigating the complex European regulatory landscape for Medical Devices and Drug-Device Combination (DDC) products. The certification ensures that Resyca's devices meet the highest safety and performance standards, significantly streamlining the EU submission process for combination products. Pharmaceutical partners can leverage this certification to accelerate market access for their inhalation therapies, reducing regulatory hurdles and ensuring EU compliance.

"This achievement is a testament to the dedication and expertise of our team," said Bernhard Müllinger, Chief Operating Officer at Resyca BV. "The MDR certification underscores our commitment to delivering high quality, patient-centric inhalation drug delivery solutions. It also strengthens our position as a trusted partner for pharmaceutical companies seeking to bring innovative therapies to market efficiently and compliantly."

The certification by TÜV SÜD Product Service confirms that Resyca has implemented a robust quality management system that aligns with the latest EU regulatory standards, ensuring the safety, performance, and reliability of its inhalation devices. By achieving this milestone, Resyca continues to demonstrate leadership in the evolving landscape of inhalation drug delivery, offering cutting-edge solutions that meet the needs of both patients and pharmaceutical partners.

## About Resyca

Resyca® was founded in 2020 and is a joint venture between Bepak and Medspray. Resyca® specialises in the development and manufacturing of compact, user-friendly soft mist inhalation and soft nasal spray devices, incorporating the proprietary Medspray micro-nozzle technology. These devices are tailored for pulmonary and nasal applications, utilising

standard pre-filled syringes / primary packaging and filling lines. As the soft mist development centre within Bepak, Resyca offers comprehensive services spanning from early-stage development through to commercial production, inclusive of filling, labelling, and packaging.

More information: [www.resyca.com](http://www.resyca.com)

### **About Bepak**

Bepak® is a global contract development and manufacturing organisation (CDMO) focused on inhaled and nasal drug delivery devices and drug-device combination products. Bepak develops and manufactures finished pharmaceutical products, as well as being a leading global supplier of drug delivery devices and componentry to the pharmaceutical industry. With a long history in the development and commercial supply of pressurised Metered Dose Inhalers (pMDIs), Bepak supplies a major proportion of the world's pMDI dosing valves and actuators, and also specialises in the industrialisation and high-volume manufacture of complex dry powder inhaler (DPI) devices. Headquartered in Holmes Chapel, UK, the company's service offering spans early-stage feasibility, analytical services and product development, from pilot-scale, through to clinical supply and commercial-scale drug product fill-finish, device and component manufacturing. More information: [www.bepak.com](http://www.bepak.com)

### **About Medspray**

Medspray is a privately owned company in Enschede, the Netherlands. With its 40 employees, Medspray focuses on the development and manufacturing of micro spray nozzles which are able to deliver soft mists. Medspray's slogan is: "tiny technology for a sustainable future." Medspray aims to contribute to a sustainable world by developing innovative spray nozzles for user-friendly health and personal care products, where a slow-moving soft spray is required, and without the use of propellants. Thanks to the high-tech nozzle chips, sprays can be tailored to suit any application, from inhalable aerosol clouds, to gentle nasal sprays, to cosmetic or fragrance sprays that do not feel wet on the skin.

More information: [www.medspray.com](http://www.medspray.com)