Press release

Croma-Pharma is the first company worldwide to achieve MDR approval in the aesthetic field

- "Saypha® RICH" is the first dermal filler to meet the strict requirements of the EU Medical Device Regulation for aesthetic treatments (MDR Annex XVI)
- Approval as a guarantee for product quality, patient safety and efficiency
- Milestone in Croma's corporate history and global growth strategy

Leobendorf, 31. October 2023 – Croma-Pharma, a global player in minimally invasive aesthetics and a leading manufacturer of high-quality hyaluronic acid syringes, has become the first industry company to achieve European certification under the Medical Device Regulation (MDR) 2027/745 for aesthetic purposes (MDR Annex XVI). The company submitted all the necessary technical and clinical documentation over the course of the past year, which was reviewed by the renowned notified body TÜV Süd (CE0123) and approved by now. This means that "Saypha® RICH" is the first of a total of seven Croma-Pharma product groups to successfully complete the strict MDR certification process. All other products from the Saypha® range will be approved by the first quarter of 2024.

"Croma is setting new standards in the field of aesthetic medicine with the MDR approval of our dermal fillers. We are proud to be the first company in the industry to comply with the strict requirements of the new EU Medical Devices Regulation," said Andreas Prinz, Managing Director of Croma-Pharma. "The certification is an important milestone in our company history and at the same time clear confirmation of our commitment to provide our customers with the safest and highest quality products."

The new regulation replaces the current Medical Devices Directive (93/42/EEC) and aims to create a transparent, sustainable and internationally recognized regulatory framework that improves the clinical safety of products and which allows fair market access to manufacturers.

"The MDR approval ensures the availability of our fillers beyond 2028. At the same time, the approval secures both European and global market access and is therefore an important component of our growth strategy," concludes Andreas Prinz.

MDR approval brings numerous advantages to patients and health care professionals (HCPs):

- Aesthetic indication: The MDR enables the certification of products with aesthetic intended use in compliance with specific rules for risk management, labelling and information for use. This will allow us to offer our customers products with non-medical aesthetic purpose.
- Safety of the patient: Products that are CE-marked according to the MDR are subject to the strictest safety requirements and stricter monitoring. In order to remain on the market, existing products must undergo an MDR review.

- Clinical evidence: MDR safety and performance compliance must be demonstrated by clinical evidence. Moreover, clinical trials conducted to provide this evidence are subject to stricter and more detailed requirements.
- Labelling: MRD CE labelling requirements include more detailed information about the nature and use of the product, potential side effects, and safety and performance information based on clinical data.
- Transparency: The Unique Device Identification (UDI) system improves trackability of medical devices in the supply chain. A central EUDAMED database enables identification of products, their manufacturers and certifications, and provides a summary of safety and clinical capacity which is publicly available for each product.

About Croma
Croma-Pharma® is a global player in the minimally invasive aesthetics market and a leading European manufacturer of premium quality hyaluronic acid syringes. The company offers a comprehensive and innovative aesthetics portfolio including botulinum toxin, fillers, lifting threads and biostimulators complemented by its own skincare brand. Founded in 1976 by the pharmacist couple Prinz, Croma-Pharma® GmbH is a family company headquartered in Austria where it also operates its manufacturing plant. With 550 employees, 13 subsidiaries in Europe and Brazil, two joint ventures and 60 exclusive export partners, it distributes its products in 80 markets globally, including the US/Canada, China and Australia/New Zealand. It also operates as a contract manufacturer in orthopaedics and ophthalmology. For more information please visit cromapharma.com.

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