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KORU Medical Systems Announces EU MDR Certification for the Freedom60® Infusion Pump With Prefilled Syringe Compatibility

MAHWAH, N.J.--(BUSINESS WIRE)-- **KORU Medical Systems, Inc. (NASDAQ: KRMD)** (“**KORU Medical**” or the “**Company**”), a leading medical technology company focused on the development, manufacturing, and commercialization of innovative and patient-centric large volume subcutaneous infusion solutions, today announced that its Freedom60® Infusion Pump, including adapter for use with 50 mL prefilled syringes, has achieved certification under the European Union Medical Devices Regulation (EU MDR 2017/745), enabling commercialization across the European Union.

The Freedom60 Infusion Pump is designed to support dosing with 50 ml prefilled syringes, while the FreedomEDGE® Infusion System provides a compatible option for 20 mL prefilled syringe formats. Together, these systems offer clinicians and patients flexibility across dosing regimens while maintaining a consistent, intuitive user experience.

EU MDR certification of both the Freedom60 and FreedomEDGE Infusion Pumps expands access to a system designed to support the growing use of prefilled syringes in subcutaneous immunoglobulin (SCIg) therapy and simplify the home infusion experience for patients.

The increasing availability of prefilled syringe formats represents an important step forward in the evolution of SCIg therapy. Published studies have shown that prefilled presentations can:

- Reduce preparation and administration step vs vials¹
- Minimize medication handling¹
- Decrease overall treatment burden²
- Improve patient confidence and independence with home therapy³

“EU MDR certification for the Freedom60 Infusion Pump marks an important step in expanding access to simpler, more patient-focused SCIg delivery across Europe,” said Linda Tharby, President and Chief Executive Officer of KORU Medical Systems. “As prefilled syringes become more widely adopted, patients are looking for solutions that reduce complexity and fit more easily into their daily routines. Our Freedom60 and FreedomEDGE systems are designed to meet that need - helping streamline therapy while maintaining the reliability that clinicians and patients expect.”

About KORU Medical Systems

KORU Medical Systems develops, manufactures, and commercializes innovative and patient-centric large volume subcutaneous infusion solutions that improve quality of life for patients around the world. The Freedom Syringe Infusion System (the “Freedom System”) currently includes the Freedom60[®] and FreedomEDGE[®] Syringe Infusion Drivers, Precision Flow Rate Tubing[™] and HigH-Flo Subcutaneous Safety Needle Sets[™]. The Freedom System, which received its first FDA clearance in 1994, is used for self-administration in the home by the patient and/or delivery in an ambulatory infusion center by a healthcare professional. Through its Pharma Service and Clinical Trials business, KORU Medical provides products for use by biopharmaceutical companies in feasibility/clinical trials during the drug development process and, as needed, is capable of customizing the Freedom System for clinical and commercial use across multiple drug categories. For more information, please visit www.korumedical.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. Actual results may differ materially from these statements due to potential risks and uncertainties such as those included under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2025, which is on file with the SEC and available on our website at www.korumedical.com/investors and on the SEC website at www.sec.gov. All information provided in this release and in the attachments is as of March 13, 2026. Undue reliance should not be placed on the forward-looking statements in this press release, which are based on information available to us on the date hereof.

1. CSL Behring LLC. *Hizentra[®] PI 10 g Prefilled Syringe Leave-Behind* (Document No. **USA-HPI-0042**; USA-HPI-0042-DEC23). Approved **Dec 21, 2023**.
2. Mallick R, Solomon G, Bassett P, Zhang X, Patel P, Lepeshkina O. *Subcutaneous immunoglobulin replacement therapy in patients with immunodeficiencies – impact of drug packaging and administration method on patient reported outcomes*. BMC Immunology. 2024;25:18. doi:10.1186/s12865-024-00608-0
3. Pandya D, Tavanti M, Hubsch A, Panaite A, Murphy E, Ramakrishna B, Mielke O. *Successful simulation of infusion pump use for IgPro20 prefilled syringes*. Poster 116. Presented at the Immunoglobulin National Society (IgNS) 13th National Conference; Oct 17–20, 2024; Washington, DC, USA. CSL Behring Medical Affairs.

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