

European Court Enforces EU MDR Rules on PRP Devices, Sending a Global Compliance Signal

Düsseldorf District Court issues preliminary injunction against Beijing Hanbaihan Medical Devices Co., Ltd. regarding non-CE-marked PRP tubes at MEDICA 2025

MONTHEY, VALAIS, SWITZERLAND, January 9, 2026 /EINPresswire.com/ -- Regen Lab SA ("Regen Lab"), a pioneer in regenerative medicine and platelet-rich plasma (PRP) technologies, announces that the District Court of Düsseldorf (Landgericht Düsseldorf, 14c Civil Chamber) has issued a preliminary injunction against Beijing Hanbaihan Medical Devices Co., Ltd. ("HBH"), also operating as Beijing Manson Technology Co., Ltd. ("Manson"), concerning PRP tubes exhibited at the MEDICA 2025 trade fair in Düsseldorf.

In its order dated 4 December 2025 (case no. 14c O 164/25), the District Court of Düsseldorf banned HBH from placing its PRP tubes on the German market unless a proper conformity assessment under the EU Medical Device Regulation (MDR 2017/745) has been carried out and the products bear a valid CE mark. The same ban applies to presenting these tubes at trade fairs if they are not MDR-compliant, not CE-marked, or not clearly labelled "for exhibition only – not for clinical use" until full compliance is achieved. The Court's order specifically references HBH's products "HA-PRP TUBE," "PRP TUBE," and "HAIR PRP TUBE," which were displayed and distributed at MEDICA 2025 without CE marking and without the required "exhibition only" notice. Each violation may be punished by fines of up to EUR 250,000 (or substitute detention). The injunction was granted urgently, without a hearing, is immediately enforceable in Germany, and remains in force unless modified in further proceedings.

For the medical community, Regen Lab's message is that, under the EU Medical Device Regulation (MDR 2017/745), PRP tubes and PRP plus hyaluronic acid (HA) tubes are medical devices and may only be supplied and used in the EU after completion of the required conformity assessment and CE marking. Regen Lab states that if a PRP device is not CE-marked under the MDR, it has not passed the required safety and performance checks and should not be used on patients.

Regen Lab further references regulatory action in China, stating that the Beijing Tongzhou Food and Drug Administration issued Administrative Penalty Decision (2018) No. 100328 against Hanbaihan Medical Devices Co., Ltd. for manufacturing and selling a "PRP KIT" classified as a Class III medical device without the required Class III registration, while its licence covered only

Class II blood-test equipment. The authority confiscated the illegal income and imposed a fine of RMB 100,000, which Regen Lab says confirms that HBH was not authorized to manufacture or sell PRP devices for human use in China.

Regen Lab also states that the “PRP” product listed by HBH/Manson in its PRC Medical Device Products Export Sale Certificate (FSC) is authorized only as blood-test equipment for medical testing or examination, not as a system for preparing platelet-rich plasma for treatment. Regen Lab alleges that marketing these blood-test tubes as a “PRP KIT” or “PRP tube” for PRP therapy, and invoking the FSC as evidence of PRP authorization, misrepresents the actual approval and may mislead users and regulators in China, the United States, and Europe. Regen Lab’s position is that a manufacturer not authorized at home to market PRP devices cannot present the same products as authorized PRP systems abroad.

In Europe, Regen Lab notes that TÜV SÜD Product Service has listed “MANSON PRP Kits” and “MANSON PRP Tubes” (Beijing Manson Technology Co., Ltd.) as non-certified products for unauthorized use of the CE0123 marking and TÜV SÜD mark following withdrawal of the certificate.

Regen Lab states that, in the United States, despite the above, these tubes continue to be promoted as fully certified “PRP” systems, including claims of U.S. FDA clearance and promotion on the website of Crown Aesthetics (acquired Revance, formerly NASDAQ-listed RVNC). Regen Lab further states that these non-conforming tubes are also promoted by Juventix Regenerative Medical, Tiger Aesthetics – Suneva, Cell Therapy Tools, NextMDLink, MazMed Inc, Wetex Medical Products, MediSupplies.com, prp-online.com, spectrum4med.com, RVT Medical, Emerging Medical Group, themedicalconciierge.com, Genesis Biologics, Integrity PRP, and Bimini Health Tech – Healeon PRP.

Legal notice: This press release describes a preliminary injunction issued by the District Court of Düsseldorf. The decision may be subject to objection or appeal. Statements regarding patent rights reflect Regen Lab’s current legal position and do not prejudice the outcome of pending proceedings.

Case reference: Landgericht Düsseldorf, Case No. 14c O 164/25.

Law firm: Rechtsanwaltskanzlei Kohn.

Firm contact: Moritz Kohn, Rechtsanwalt, Ferdinand-Happ-Str. 14 B, 60314 Frankfurt am Main, Germany.

Email: moritz.kohn@kanzlei-kohn.de

Website: www.kanzlei-kohn.de

Dr. Giuseppe Calloni

RegenLab USA LLC

+1 332-999-6604

[email us here](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/881549360>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2026 Newsmatics Inc. All Right Reserved.