

## **Capillary Biomedical Receives ISO 13485:2016 Quality System Certification**

Irvine, CA – February 22, 2022 – Medical device developer [Capillary Biomedical, Inc.](#) (CapBio) has announced that it has received [ISO 13485:2016](#) (“Medical devices – Quality management systems – Requirements for regulatory purposes”) certification, indicating that CapBio’s quality management system conforms to the recognized international standard for the design, manufacture, and distribution of medical devices. The certification demonstrates that the company’s quality system is aligned with EU regulations and ready to support commercialization of the company’s SteadiSet infusion set in the EU upon CE Marking.

ISO 13485:2016 is an internationally recognized quality standard intended to provide a quality framework focused on the consistent design, development, servicing and sale of medical devices. To be certified, organizations must demonstrate an ability to comply with the requirements of the standard through documented procedures and supportive evidence.

“Our mission at CapBio is to develop and commercialize quality products that reduce the burden of living with diabetes. This ISO certification is evidence of our commitment to the highest standards of product performance, quality, consistency, and reliability,” said CapBio CEO Paul Strasma. “This is another milestone for the company in what is shaping up to be our most important year to date.”

News of the ISO certification arrives on the heels of CapBio’s announcement last month that it has received investigational device exemption (IDE) approval from the US Food and Drug Administration (FDA) to start a pivotal trial for the assessment of its seven-day wear infusion set technology.

CapBio’s SteadiFlow “kink-proof” infusion sets are designed to significantly extend patient wear time to seven days and maintain insulin stability.

Best-in-class clinical feasibility study results were announced at last year’s American Diabetes Association (ADA) Scientific Sessions meeting. At that event, results from a study performed at St. Vincent's Hospital in Melbourne, Australia showed 88% of infusion sets featuring CapBio’s SteadiFlow cannula technology lasting the intended seven days. These data are a significant improvement over

current commercial infusion sets, which have been shown in published studies to last 3-days from 75–85% of the time and 7-days only 33–50% of the time.

CapBio's SteadiSet infusion set, powered by its SteadiFlow technology, is designed to significantly extend patient wear time of insulin infusion sets to seven days and maintain insulin stability by addressing the common causes of infusion site failure. The SteadiSet also features an integrated inserter designed for easy, painless, hidden needle, one-handed insertion. SteadiFlow cannula technology features a soft and flexible cannula designed to move with the body tissue during physical activity, increasing comfort while greatly decreasing tissue damage and inflammation.

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*Capillary Biomedical, Inc. (CapBio), headquartered in Irvine, California, is focused on simplifying insulin pump therapy to improve the quality of life for people with diabetes. The Company's first product, the SteadiSet™ infusion set featuring SteadiFlow™ technology is designed to improve the comfort, reliability and predictability of insulin pump therapy. Learn more about Capillary Biomedical by visiting [www.capillarybio.com](http://www.capillarybio.com).*

*To obtain illustrations, more information, or to conduct interviews with Capillary principals, contact Paul Williams at [paul@medialinecommunications.com](mailto:paul@medialinecommunications.com) or 310/569-0023.*