



BIOCORP obtains 510(k) FDA clearance for SoloSmart[®], Sanofi's smart cap for disposable insulin pens.

- In addition to SoloSmart's CE marking (Sept 2022), the FDA's authorization reinforces BIOCORP's technological leadership in the smart pens market.
- This is the second FDA clearance¹ for Biocorp's Mallya platform.

Issoire (France), January 25, 2023, at 7:30 am CET – BIOCORP, a Novo Nordisk company based in France and specialized in the design, development, and manufacturing of innovative medical devices, announced today that they have received 510(K) clearance from the U.S. Food & Drug Administration (FDA) to market SoloSmart[®], Sanofi's smart medical device that connects SoloStar[®] insulin pens.

Eric Dessertenne, CEO of BIOCORP, said: *"This approval is a major achievement for SoloSmart and our commercial partner, Sanofi. We have brought together our unique expertise in medical devices and innovative therapies to allow the commercial launch of SoloSmart in the United States, answering to patients' needs to simplify their treatment journey. It also illustrates BIOCORP's ability to meet the highest regulatory requirements and reinforces the Mallya platform as the best in class in the smart pen market".*

Designed, developed, and manufactured exclusively for Sanofi by BIOCORP, SoloSmart is a smart sensor that is directly attached to Sanofi's SoloStar insulin pen platform, upgrading the pens into connected devices. SoloSmart automatically collects and records key treatment information (selected insulin units, date, and time of injection) and transmits it to a dedicated digital application. It offers HCPs an easy way to follow patients in the case of a multitherapy treatment, for instance when using basal and rapid insulins.

ABOUT BIOCORP

Recognized for its expertise in the development and manufacture of medical devices and delivery systems, BIOCORP has today acquired a leading position in the connected medical device market thanks to Mallya. This smart sensor for insulin injection pens allows reliable monitoring of injected doses and thus offers better compliance in the treatment of patients with diabetes. Available for sale from 2020, Mallya spearheads BIOCORP's product portfolio of innovative connected solutions. BIOCORP was acquired by Novo Nordisk in 2023.

For more information, please visit www.biocorp.fr.

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¹ BIOCORP obtained 510(k) clearance for Mallya first version in December 2022. See PR edited on Dec 7th, 2022, on Biocorp's website www.biocorp.fr.