BIOCORP announces its certification to the new European Medical Device Regulation

Issoire (France), December 20th, 2022, at 7:30 am CET – BIOCORP (FR0012788065 – ALCOR / Eligible PEA-PME), a French company specialized in the design, development, and manufacturing of innovative medical devices, announced today that they have received the EU production quality assurance certificate according to the new regulation for non-sterile medical devices with measurement function for drug administration.

This new European regulation 2017/745, which came into force on May 26, 2021, offers an important development to strengthen the safety of medical devices in the interest of patients.

Eric Dessertenne, CEO of BIOCORP, said: *"We are delighted to announce our compliance with this new European regulation. Indeed, to date, nearly 40% of the requests from device manufacturers have been refused. This certification obtained by BIOCORP required more than a year of work with the notified body. Our Quality Management System (QMS) complies with the requirements for the production and monitoring of medical devices, which can continue to be sold as is until November 2027 and later on. This guarantees our pharmaceutical customers the long-term supply of our production and secures any supply disruption. At the same time, this announcement secures to a large extent our production jobs at our historical site in Issoire."*

The new European medical devices regulation (Eu MDR), as described, has been strengthened in several areas. First, requirements for manufacturers before marketing a medical device have been strengthened. These include the obligation to set up evaluations and investigations proportionate to the level of risk to ensure the effectiveness and safety of use of all these devices for the patient's benefit.

In addition, data transparency has been strengthened through the new European database EUDAMED, which will soon contain detailed information about medical devices available in Europe, including reported incidents and the progress of clinical investigations.

Finally, the procedures for authorizing the notified bodies responsible for issuing CE marking certificates and post-market surveillance have been significantly strengthened.

All of these requirements aim to ensure the safe use of medical devices while promoting access to innovation to offer new solutions for patient care. The new regulation also provides for better European collaboration.

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. The company has 80 employees. BIOCORP is listed on Euronext since July 2015 (FR0012788065 – ALCOR).
For more information, please visit www.biocorpsys.com.

CONTACTS BIOCORP

Sylvaine Dessard
Senior Director Marketing & Communication
rp@biocorp.fr
+ 33 (0)6 88 69 72 85

Bruno ARABIAN
Press Officer
barabian@ulysse-communication.com
+33 (0)6 87 88 46 26

ELIGIBLE PEA PME

ALCOR LISTED EURONEXT