

Press Release

Innovative hydrogel "mediNiK®" from Purenum GmbH receives CE mark

Milestone achievement for medtech start-up in Bremen on the way to marketing an innovation for kidney stone patients

Bremen, 19 July 2021 - Purenum GmbH, a start-up specializing in innovative medical hydrogels and adhesives, announced the successful CE certification of its first product development. The quality management system required for medical products in accordance with the international ISO standard 13485:2016 was already audited and certified by TÜV Nord CERT GmbH in July 2020. The first surveillance audit could already be successfully completed "on its own feet" this year.

In the European Union, a CE mark is required for the marketing of a medical device which certifies the compliance with all relevant standards and laws.

The spin-off of the Fraunhofer IFAM in Bremen was supported by Activoris Medizintechnik GmbH for certification of the quality management system and in the implementation of the conformity assessment procedure. Also, Activoris initially provided the quality management representative as a service.

Manfred Peschka, CEO of Purenum GmbH commented: "The CE marking of our hydrogel "mediNiK®" in combination with the establishment of a quality management system is an important milestone in our still young company development. We have now created the know-how and defined the processes to successfully bring further innovations through the necessary approval processes."

"We are delighted with the innovative research team about this important success!" said Axel Fischer, CEO of Activoris Medizintechnik GmbH. "We have been accompanying Purenum from the very beginning on its way from a product idea to a professional medtech company, which is now taking big steps towards commercialization. We are convinced that the "mediNiK" system will decisively improve the removal of kidney stones," says the medical device specialist from Gemünden.

About mediNiK® - Help for surgical removal of kidney stones

Many millions of people worldwide suffer from kidney stones, mostly to be removed by surgical/endoscopic procedures. However, residual stones may remain after treatment. For example, because they are too small to grasp or difficult to access in the renal calices. If these do not come off naturally, they remain in the kidney.

With "mediNiK®", Purenum is developing a medical adhesive for the removal of kidney stone fragments to remove these residual stones. The mediNiK system consists of a biological hydrogel which embeds the residual stones in a matter of seconds and thus makes them removable by means of gripping methods used in the flexible URS.

About Purenum GmbH - "We stick to the Future"

Life without adhesives is hard to imagine - in many areas of daily life we have direct or indirect contact with adhesives. This not only in technology & medicine, but also in nature. Purenum GmbH develops and researches new adhesive systems for applications in the field of medicine, especially those systems that are used as medical products on or in the patient. However, the consulting services also cover technical adhesives, such as those used in the manufacture of medical devices (or other application scenarios).

The financing of Purenum GmbH is secured by various private and public investors.



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About Activoris Medizintechnik GmbH



Activoris Medizintechnik GmbH in Gemünden, Germany is a service company for contract manufacturing, medtech development and strategic consulting for companies in the life science and pharmaceutical industry. Clients are established companies as well as innovative startups from the biotech, medtech and pharma industry. Activoris' outsourcing services enable them to achieve greater flexibility, cost efficiency and faster market access. Activoris operates locations in Gemünden (Wohra), Munich and Schwalmstadt. Axel Fischer, +49 (0) 6453.58535.10, axel.fischer@activoris.com.