

Bactiguard receives first MDR product approval

Bactiguard today announces its first MDR (Medical Device Regulations 2017/745) product approval following a comprehensive authorization process. The MDR approval relates to the latex BIP Foley Catheter which is an indwelling urinary catheter with Bactiguard's unique infection prevention technology.

Bactiguard's patented technology is based on a thin noble metal alloy coating attached to the catheter surface. When in contact with fluids, the metals create a galvanic effect which reduces microbial adhesion where fewer bacteria adhere to the catheter surface. Today, one out of ten patients worldwide are affected by healthcare associated infections (HAI) and catheter-associated urinary tract infections (CAUTI) stand for a considerable part. Urinary catheters with Bactiguard's technology reduce the risk of CAUTI significantly.

- Patient safety always comes first for Bactiguard, and stricter regulations are an advantage to us. Products scrutinized in the MDR-process are audited through higher standards of quality and safety. The BIP Foley catheter made it through this thorough process and will not only improve patient safety by reducing the risk of HAI but also by reducing the use of antibiotics. A powerful combination with positive impact on both patients and a healthier world, says Fatima Stensvad Flodin, Bactiguard's Chief Quality & Regulatory Officer.

The new MDR regulations were adopted as per May 26, 2021, to ensure that only non-harmful equipment used on patients and by care takers is allowed on the European market. The regulatory landscape is complex and Bactiguard will continue to carefully monitor various new demands and requirements, set by both the market and regulatory agencies, on medical devices.

- Gaining the MDR-approval for the BIP Foley Catheter is a first step but an important achievement for us, it is a formal acknowledgement of our work on quality and safety, and this will pave the way also for future product approvals. The BIP Foley urinary catheter is one of Bactiguard's products that combats HAI and our ambition is to remain at the forefront of both complying with the highest regulatory requirements and continuing to bring safe infection solution technology and products to the market. And ultimately, make them accessible to more patients, says Anders Göransson, Bactiguard's CEO.

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About Bactiguard

Bactiguard is a Swedish medical device company with a mission to save lives. To achieve this mission, we develop and supply infection prevention solutions which reduce the risk of infections and the use of antibiotics. This way, we save significant costs for healthcare and the society at large.

The Bactiguard technology is based on a thin noble metal alloy coating that prevents bacterial adhesion and biofilm formation on medical devices. Bactiguard offers the technology through licence agreements and our BIP (Bactiguard Infection Protection) portfolio of products. Urinary catheters with the Bactiguard technology are market leading in the USA and Japan through our licensing partner BD, and in 2021 orthopaedic trauma implants, ZNN Bactiguard, were launched by Zimmer Biomet. Bactiguard's product portfolio also includes a non-alcoholic product line for wound care and disinfection. It effectively kills microbes while being biocompatible and tissue friendly.

Bactiguard is in a strong expansion phase in the markets in Europe, China, India, the Middle East and Southeast Asia through our own product portfolio and by establishing licensing deals in new therapy areas. Bactiguard has about 210 employees around the world. Its headquarters and one of three production facilities are located in Stockholm, the other two in Malaysia. Bactiguard is listed on Nasdaq Stockholm.

Read more about Bactiguard: www.bactiguard.com

