The US Food and Drug Administration Grants First-Ever De Novo (Ultraviolet radiation disinfection chamber device) for Germitec's Chronos®, a Chemical-Free UV-C High-Level Disinfection (HLD) Device for Endocavitary and External Ultrasound Probes

- Infection prevention is a significant global public health issue and a top priority for the US healthcare system.
- Each year, 1.7 million patients in the US contract Healthcare-Associated Infections (HAIs), leading to 99,000 deaths[1].
- During the rigorous FDA's De Novo process, Chronos® effectiveness was evaluated against bacterial spores, vegetative bacteria, mycobacteria, yeast/molds (spores), spore forming molds and virus, and demonstrated that the UV disinfection device was able to achieve microbial log reduction of a panel of clinically relevant and UV resistant microorganisms, as appropriate for the intended level of disinfection (a High-Level Disinfection) of the device.
- Chronos® offers healthcare professionals a user-friendly, traceable and chemical-free one-button solution.

Bordeaux, France, and San Diego, California – September 4, 2024 – Germitec, an innovative French MedTech company specializing in High-Level Disinfection (HLD) for ultrasound probes through its unique proprietary UV-C technology, is pleased to announce that the FDA has granted first-ever De Novo for its Chronos® automated disinfection device.

Through the De Novo classification process, FDA concludes that this device should be regulated under Regulation Number 21 CFR 880.6511 and classified as a Class II medical device.

Ultrasound, a widely used medical imaging technique, is experiencing rapid growth, with an estimated market size expected to exceed $4 billion by 2024[2]. This growth is driven by advanced technologies, a rising prevalence of chronic diseases, and expanding healthcare infrastructure. According to the Spaulding Classification, ultrasound probes are considered semi-critical devices that require High-Level Disinfection depending on their use. Improper disinfection can lead to cross-contamination, resulting in Healthcare-Associated Infections (HAIs) such as hepatitis B, C, or human papillomavirus (HPV) highly resistant and transmissible[3,4].

Scientific data indicate that 13% of vaginal probes used with sheaths test positive for HPV even after disinfection with wipes[5], and up to 70% of HAIs could be prevented with effective infection prevention and control measures[6]. HAIs claim the lives of 99,000 patients annually in the US and pose a serious threat to healthcare safety, as reported by the Centers for Disease Control and Prevention (CDC). These infections are linked to hygiene practices surrounding the procedure and the management and disinfection of the probes themselves.

Germitec's mission is to enhance standards of care by reducing the risk of cross-contamination. Their solution, Chronos®, is a one-button, chemical-free automated device that has proven safety and efficacy. The UV-C technology used in Chronos® penetrates the membrane of microorganisms, disrupting their DNA, RNA, and cellular proteins, thereby halting their replication and capacity to infect, hence dramatically reducing cross-contamination.

Chronos® is the first and only UV-C HLD chamber granted by the FDA for marketing and distribution in the US. It is indicated for use in a healthcare environment to achieve, in about 90 seconds[7], High-Level Disinfection at the point of care of surfaces of external, transvaginal, and transrectal ultrasound probes that do not contain lumens and indentations or channels that are deeper than their widths. These probes are widely used across various medical departments, including Gynecology & IVF, Urology, Radiology, Emergency Medicine, Anesthesia, and Biopsy.

Dr. David J. Weber, MD, MPH, Sander Distinguished Professor and Medical Director of the Department of Infection Prevention at UNC Medical Center, and a leading expert in infectious diseases and infection prevention, commented: "UV-C HLD is a proven and efficient technique, supported by multiple independent studies. With the increasing demand for ultrasound exams, this product offers healthcare professionals an all-in-one solution that is significantly faster, sustainable, cost-effective, repeatable, and traceable, ultimately improving patient safety. I have no doubts about the benefits of this technology."

Vincent Gardès, Chief Executive Officer of Germitec, stated: "Being granted FDA De Novo is an outstanding achievement for Germitec. This milestone is the result of several years of hard work by a first-class team and our partners. We are excited to introduce this groundbreaking chemical-free technology to the world's largest healthcare market. With the successful completion of the rigorous FDA De Novo process, our UV-C HLD solution offers validated microbial kill efficacy, providing healthcare facilities with a trusted option to protect their patients across all departments where ultrasound exams are performed. Additionally, this Clearance paves the way for our future UV-C HLD products designed for long probes used in ENT and Cardiology departments."

About Germitec

Founded in 2005 by the Deshays family, Germitec is an innovative French MedTech company specializing in High-Level Disinfection for ultrasound probes using proprietary UV-C technology. The company safeguards over 2 million patients annually across EMEA, APAC, and South America and is present in over 40 countries through an extensive network of distributors.

For more information, visit www.germitec.com and connect with us on LinkedIn and X.

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