Case Medical, Inc.
Originators of MediTray®, SteriTite® and Case Solutions®

FOR IMMEDIATE RELEASE: July 31, 2024

Case Medical Receives New FDA510k

For its SteriTite Universal Container System

Bloomfield, NJ – July 31, 2024 – Case Medical announced today that the company received a new FDA 510k for the SteriTite® Universal Container System and MediTray products. The SteriTite® container system is a family of a rigid, reusable, sterilization containers and inserts used to enclose medical devices and instrument sets for sterilization, transport, and storage. The SteriTite container and MediTray products have been previously cleared for use in steam as well as low temperature sterilizers. The new 510k clearance demonstrates that the Case Medical SteriTite Universal Container with solid base previously cleared for pre-vacuum steam, EO, and TSO3 VP4, can now be used for Steris V-Pro maX, V-Pro maX2, V-Pro s2, and V-Pro 60.

Case Medical's line of containers are universally compatible with all devices that can be sterilized. Now, health care facilities can standardize utilizing the SteriTite solid bottom container with filters in lid only. This configuration increases turnaround, reduces the total weight of the device, eliminates user error, and provides less points of potential ingress for bacteria and other environmental contaminants.

Case Medical, Inc. follows the "overkill method" of sterility assurance to show an elimination of a biological challenge and validated a one year (365 days) event related shelf life. All SteriTite containers were validated with inner baskets, trays and inserts representative of the company's MediTray® line of products. Testing was designed to simulate worst-case scenarios with half cycles and end of shelf-life concentrations of hydrogen peroxide. The validation testing was conducted at independent laboratories in accordance with FDA guidance and available ANSI/AAMI standards such as ANSI/AAMI ST77, AAMI TIR 12 and ANSI/AMMI ST79.

Please refer to the company's website for more information including the Case Medical FDA 510k listing and for access to the IFU.
Caution: Perforated bottom SteriTite containers must be used for gravity displacement steam sterilization and for STERRAD sterilizers. STERRAD units have not been validated at this time with solid base.

About Case Medical
Case Medical is a US based, vertically integrated manufacturer of medical devices and products for sterilization and infection prevention. Case Medical is an FDA registered and ISO-13485, ISO-27001 certified medical device manufacturer. Our reusable sterilization containers and instrument chemistries meet the highest standards for patient safety and environmental preference. Visit our website www.casemed.com for more information about our company and our products for infection prevention.

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