



MedNet expands its portfolio of non sterile CE marked components with stopcocks and manifolds manufactured by Elcam Medical

Münster 2020/06/16- MedNet, supplier and manufacturer of medical and pharmaceutical components, assumes responsibility for the regulatory support for CE certification of the stopcocks and manifolds from the world market leader Elcam Medical and is now able to offer them CE marked in non sterile version.

“In the regulatory area, MedNet is well positioned because it has an established workflow and access to the appropriate resources. The certification by MedNet gives us the opportunity to offer our mutual customers in Europe the maximum regulatory support,” explains Amir Bohadana, Sales Executive Director at Elcam Medical, in the decision to outsource the regulatory support to MedNet.

MedNet has sold Elcam components on the European market for more than 30 years. In addition to sales, MedNet has been supporting the registration of international medical devices for the European market for over 20 years and has also launched its own product line in 2013.

With the CE mark on the non-sterile component, MedNet is responding to the needs of medical device manufacturers all over Europe, who are faced with higher regulatory requirements coming into effect. Every component of a device or set now requires a technical file, which increases the regulatory effort and the hurdles for innovations. “Small companies don't have the staying power until the registration is completed. Providing CE certificates for individual non-sterile components simplifies the preparation of the product file and significantly reduces the time required for a market launch”, explains Ole Stein, Managing Director at MedNet.

With the purchase of the non sterile CE marked components, medical device manufacturers save the regulatory effort. In addition to time and financial savings, it also increases planning reliability for new developments and sets.



For Custom Procedure Tray providers who in accordance with Article 12 MDD / Article 22 MDR depend on a CE mark for their components, the purchase of the non-sterile version saves the additional unpacking / packaging effort and bypasses the problem of a second sterilization in the set compared to the packaged, sterile medical device.

In addition to the Elcam stopcocks and manifolds, MedNet offers various non sterile CE marked components from the field of fluid management as well as for angiography and interventional cardiology / radiology.

Since 1990 **MedNet GmbH** has been a competent service provider and supplier for the medical device and pharmaceutical industry. As an European company with headquarters in Germany we offer a wide portfolio in standard components from well-known manufacturers as well as our own product lines for interventional radiology, infusion technology and others. Furthermore you can benefit from our worldwide well established network offering comprehensive material and manufacturing technologies customized to your individual requirements. With its extensive expertise on medical applications, MedNet ensures the best solution for your development or application. MedNet is ISO 13485 certified.

Elcam Medical is a world class producer of disposable medical devices and components for the OEM market, and a provider of innovative solutions for specialized flow control needs. Elcam Medical strives to provide the building blocks for a safer and more effective fluid management in medical areas such as IV Therapy, Vital Signs Monitoring, Interventional Cardiology & Radiology and Dialysis. We do so with a comprehensive understanding of the medical and clinical environment and through partnering with our customers who are the medical industry's leading companies.