## News Release



## Portescap's Brushless DC motor manufacturing plant achieves ISO 13485 certification for respirators

Portescap's production facility which manufactures the company's slotless brushless DC motors for use in respirators has been recognized as compliant with ISO 13485:2016. The organization's management compliance will give further confidence to respirator OEMs requiring accurate and reliable motor control manufactured to consistent and exacting standards.

Confirmation that the design, development, manufacturing and sales of slotless brushless DC motors complies with the ISO 13485 standard meets a requirement for many manufacturers of medical devices. The standard extends on ISO 9001 and contains specific and stringent requirements which include traceability of parts and a risk-based approach from the initial design stage onwards. Process and software validations at defined intervals as well as medical device compliance and regulations are also required. The management system certificate was presented by independent risk management and quality compliance firm, DNV GL.

For manufacturers of respirators and medical equipment, Portescap's ISO 13485 compliance contributes to their quality management system to demonstrate aspects including consistency in design, development, and production, as well as storage and distribution.

ISO 13485 management system compliance at Portescap's 72,000 sq. ft. design and manufacturing facility located in Mumbai, India, demonstrates that its products have been manufactured to recognized standards. ISO certification contributes to assurances on safety as well as production processes standards for medical devices.

To meet compliance, Portescap reviewed its existing processes and further improved on risk mitigation as well as compliance and regulatory adherence. The plant itself includes over 1,100 staff and hosts in-house machining, winding and injection molding capabilities as well as an ESD safe assembly facility.

Portescap's Brushless DC motors are favored for respirator applications because of their characteristics including speed and precision of control. With a compact footprint as low as 13mm diameter, Portescap's slotless brushless DC motors have nominal torque ratings between 1.7 to 275 mNm at speeds up to 90,000 rpm. For respirator manufacturers, Portescap's brushless DC motors provide low inertia for high acceleration, as well as smooth motion as a result of the slotless design. They also emit low noise and vibration and are high efficiency for battery-powered devices.

## About Portescap

Portescap offers the broadest miniature and specialty motor products in the industry, encompassing coreless brush DC, brushless DC, stepper can stack, gearheads, digital linear actuators and disc magnet technologies. Our products have served diverse motion control needs in a wide spectrum of applications including medical, life science, instrumentation, automation, aerospace and commercial for more than 70 years.

Portescap has manufacturing centers in the United States and India, and utilizes a global product development network with research and development centers in the United States, China, India and Switzerland.