



Sandstone Diagnostics Achieves ISO 13485:2016 Certification

International Certification Ensures Company's High Quality Management System for the Design and Manufacture of Medical Devices

PLEASANTON, CA, USA, October 8, 2019 /EINPresswire.com/ -- [Sandstone Diagnostics](#), a medical device company committed to making high quality clinical testing ubiquitous, is pleased to announce that the company has received the International Organization for Standards (ISO) 13485:2016 certification for its Quality Management System (QMS). ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes, is an international standard specific to the medical devices industry. Sandstone's certification is issued by GMED North America, the US subsidiary of GMED, the largest French Notified Body.

"We are pleased to have achieved this voluntary milestone for our Quality Management System," said Sandstone's CEO Karen Drexler. "ISO 13485 certification is an important step in ensuring that Sandstone maintains the highest standards for the design, development, and manufacture of our medical devices, and signals our commitment to quality to our customers."

Sandstone is the developer and manufacturer of the [Trak[®] male fertility testing system](#), an FDA-cleared consumer device that enables men to test their sperm count and semen volume at home. Trak helps lower the barriers to fertility testing and management for couples trying to conceive. Trak employs CentriFluidic™ technology, developed by scientists from Sandia National Laboratories. Sandstone's portable CentriFluidic technology combines fundamental centrifugal separation principles with mesofluidic design to unlock new capabilities in healthcare and clinical diagnostics.

Sandstone is currently developing the Torq™ zero delay centrifuge system, a CentriFluidic device that provides immediate blood plasma isolation and stabilization at the point of collection. The Torq system comprises a compact, battery-powered centrifuge and uniquely designed discs that collect and spin blood samples immediately following collection to hermetically isolate plasma from blood cells and other contaminants. The Torq system provides superior sample purity and stability compared to existing blood collection technologies and is adaptable to a wide range of diagnostic applications. Torq systems are currently deployed in investigational evaluations.

About Sandstone Diagnostics.

Founded in 2012 in part by government scientists from Sandia National Laboratories, Sandstone's mission is to make high quality medical testing ubiquitous by bringing powerful, portable CentriFluidic™ Technology to the point of care. Learn more at www.sandstonedx.com.

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