

## **S.D. Sight Diagnostics Ltd. Quality and Compliance Code**

*Last updated: September 2020*

At Sight Diagnostics<sup>®</sup> we place the highest value on quality. As such, quality is an essential part of Sight's goals and processes.

Sight's Quality Management System policies define our arrangements for managing operations and activities across all disciplines and at all levels within the company in accordance with the framework established by FDA Quality System Regulation (21 CFR Part 820) and ISO 13485.

Our Regulatory Affairs department manages registrations and listings with FDA and all other regulatory authorities in territories in which Sight holds business.

To learn more about our regulatory and compliance approach, please refer to the information and links below:

- **Quality Policy:** Our policy is to provide products and services that exceed customer requirements for safety, reliability and effective performance. We achieve this Policy through Management and Associate commitment to customer satisfaction, continuous improvement, compliance with requirements and the maintenance of an effective Quality Management System.
- **ISO Certification:** Sight has been certified to ISO 13485 since 2015. A copy of our ISO certificate is available [here](#).
- **FDA Registration:** Manufacturers of all medical devices are required to register their establishments and list their devices with FDA. To view registrations and listings on FDA's database, click [here](#).
- **TGA registration (Australia):** to view registrations and listings on the TGA database, click [here](#).
- Sight OLO's authorised representative in Europe (CE mark) is CE Partner 4 U.

### **Sight OLO<sup>®</sup>'s Indications for Use**

Sight OLO is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening capillary or venous whole blood samples collected in K<sub>2</sub>EDTA

blood collection tubes, or fingertip samples collected using the Sight OLO test kit microcapillary tubes.

When used with the Sight OLO cartridge, the Sight OLO enumerates the following CBC parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO %/#, EOS%/#, and BASO%/#.

Sight OLO is indicated for use in point of care and clinical laboratories to identify and classify one or more of the formed elements of blood in children 3 months and above, adolescents and adults.

### **Important safety information on Sight OLO**

- Please refer to the analyzer's Operator's Manual, or to FDA registration listing, for detailed analyzer performance specifications.
- Please read the Operator's Manual provided by the manufacturer prior to operating the analyzer.