



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	339854	DIAGNOSTX PTY LTD - Instrument/analyser IVDs
ARTG entry for	Medical Device Included - IVD Class 1	
Sponsor	DIAGNOSTX PTY LTD	
Postal Address	2 Tawny Court, Aberfoyle Park, SA, 5159 Australia	
ARTG Start Date	20/07/2020	
Product Category	Medical Device Class 1	
Status	Active	
Approval Area	IVD	

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
S.D. Sight Diagnostics Ltd	23 Menachem Begin Road , Tel Aviv, 6618004 Israel

Products

1 . Instrument/analyser IVDs

Product Type	IVD	Effective Date	20/07/2020
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GMDN CT943 Instrument/analyser IVDs

Intended Purpose Sight OLO is a novel point-of-care Haematology analyzer that performs complete/Full blood count (CBC/FBC) analysis from capillary or venous whole-blood samples. The analyzer is based on breakthroughs in machine-vision technology that are enabled by proprietary automated fluorescence microscopy and a novel sample preparation and staining method. The OLO platform accepts disposable per-test cartridges. OLO's sophisticated failsafe system is designed to detect any errors in the process, in order to essentially eliminate the risk of erroneous results. 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%/#. The 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.

Specific Conditions

No Specific Conditions included on Record

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