



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 345293 Point Of Care Diagnostics Australia Pty Ltd - Haematology full blood count IVDs

ARTG entry for Medical Device Included - IVD Class 2

Sponsor Point Of Care Diagnostics Australia Pty Ltd

Postal Address PO Box 780, ARTARMON, NSW, 1570
Australia

ARTG Start Date 1/10/2020

Product Category Medical Device Class 2

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
PixCell Medical Ltd	6 Hayezira Street PO Box 113 Yokneam, Ilit, 2069202 Israel

Products

1 . Haematology full blood count IVDs

Product Type	IVD	Effective Date	1/10/2020
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GMDN CT878 Haematology full blood count IVDs

Intended Purpose IVDs that are intended to be used for the qualitative and/or quantitative haematological determination of measured and/or calculated whole blood cell parameters.

Specific Conditions

No Specific Conditions included on Record

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