



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	406571	Device Technologies Australia Pty Ltd - Multiple-viruses IVDs
<b>ARTG entry for</b>	Medical Device Included - IVD Class 3	
<b>Sponsor</b>	Device Technologies Australia Pty Ltd	
<b>Postal Address</b>	Locked Bag 521, FRENCHS FOREST, NSW, 2086 Australia	
<b>ARTG Start Date</b>	21/03/2023	
<b>Product Category</b>	Medical Device Class 3	
<b>Status</b>	Active	
<b>Approval Area</b>	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
Lucira Health Inc	1412 62nd Street Emeryville, CA, 94608 United States Of America

### Products

#### 1 . Multiple-viruses IVDs

<b>Product Type</b>	IVD	<b>Effective Date</b>	21/03/2023
<b>GMDN</b>	CT702 Multiple-viruses IVDs		
<b>Intended Purpose</b>	The Lucira COVID-19 & Flu Test is a single use real-time RT-LAMP Nucleic Acid Amplification Test (NAAT) in vitro diagnostic for the simultaneous qualitative detection and differentiation of SARS-CoV-2, Influenza A and Influenza B directly from nasal swab samples. This test is intended for use by a healthcare professional at Point of Care in individuals who are symptomatic.		

### Specific Conditions

No Specific Conditions included on Record

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