



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375090	Calibre Products Pty Ltd - Eye splash shield, single-use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Calibre Products Pty Ltd	
Postal Address	PO Box 200, Tullamarine, VIC, 3043 Australia	
ARTG Start Date	22/09/2021	
Product Category	Medical Device Class 1	
Status	Active	
Approval Area	Medical Devices	

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
Shenzhen Eaststar Technology Co Ltd	2F Building 26 Area A First Industrial Zone Gonghe Shajing Baoan, Shenzhen, China

Products

1 . Eye splash shield, single-use

Product Type	Single Device Product	Effective Date	22/09/2021
GMDN	58376 Eye splash shield, single-use		
Intended Purpose	Face Shield intended for the protection of the eyes and face of healthcare workers. This is a single use, non sterile device.		

Specific Conditions

No Specific Conditions included on Record

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