

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 334570 Me 3D Pty Ltd - Shield, face

ARTG entry for Medical Device Included Class 1

Sponsor Me 3D Pty Ltd

Postal Address iAccelerate University of Wollongong, North Wollongong, NSW, 2500

Australia

ARTG Start Date 18/04/2020

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

Me 3D Pty Ltd iAccelerate University of Wollongong

North Wollongong, NSW, 2500

Australia

Products

1. Shield, face

Product Type Single Device Product Effective date 18/04/2020

GMDN 11961 Shield, face

Intended purpose Shield, Face.

This is a face shield worn by medical staff to provide protection against suspended liquids. Comprising 3

parts, a clear shield a plastic frame and an optional retaining elastic.

Specific Conditions

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