

# CERTIFICATE

Number: 3819042

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## Aroa Biosurgery Ltd.

2 Kingsford Smith Place, Airport Oaks  
2022 Auckland  
New Zealand

Manufacturer DUNS 59-454-0572

Conforms with the following standard and regulatory requirements:

## ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009

Canada: Medical Devices Regulations - Part 1- SOR 98/282

United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

### Scope:

The design and manufacture of sterile ovine collagen based wound dressings and soft tissue reinforcement products.

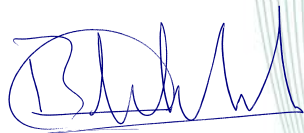
Certificate expiry date: 2022-1-6

Certificate effective date: 2020-10-30

Certified since: 2018-1-6

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:

<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



# ADDENDUM

To certificate: 3819042

The management system of the organization(s) and/or location(s) of:

## Aroa Biosurgery Ltd.

2 Kingsford Smith Place, Airport Oaks  
2022 Auckland  
New Zealand

Certified organization(s) and/or locations:

Different scope

Aroa Biosurgery Ltd.  
32 Amelia Earhart Ave  
Airport Oaks  
2022 Auckland, New Zealand

Warehousing  
Manufacturer DUNS # 59-454-0572

Aroa Biosurgery Ltd.  
7220 Trade St. Suite 252  
92121 San Diego, CA  
United States Of America

Warehousing and Distribution  
DUNS # 081203920

Addendum expiry date: 2022-1-6  
Addendum effective date: 2020-10-30

