

Certificate of Approval

This is to certify that the Management System of:

Oxtex Ltd

Windrush Innovation Centre, Windrush House, Burford Road, Witney, OX29 7DX, United Kingdom

has been approved by LRQA to the following standards:

ISO 13485:2016



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current issue date: 1 March 2019

Expiry date: 28 February 2022

Certificate identity number: 10175809

Certificate Approval No: LRQ00000415

Original approval(s):

ISO 13485 – 2 December 2016

Product number: ISO 13485 – 00006512

The scope of this approval is applicable to:

Design, development and manufacture of self-inflating hydrogel and silicone based medical devices.



001