

Certificate of Approval

This is to certify that the Management System of:

Sterima N.V.

Zonnekestraat 13, 8501 Bissegem, Belgium

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 February 2019
Expiry date: 31 January 2022
Certificate identity number: 10169282
Certificate Approval No: LRQ0959129/A

Original approval(s):
ISO 13485 – 28 January 1998

Product Approval number: ISO 13485 – 0003595

The scope of this approval is applicable to:

Design and manufacturing of haemodialysis solution concentrates. Manufacture and sterilisation of standard procedure sets and trays. Distribution of medical devices. Cleaning, packaging and sterilisation of loan instruments for orthopaedic and spinal intervention.



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