

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

This is to certify that the Quality Management System of:

**Sterima N.V.
Zonnekestraat 13,
8501 Bissegem
Belgium**

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 0959129/D
Original Approval: 28 January 1998
Current Certificate: 16 September 2019
Certificate Expiry: 31 January 2022

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited

**EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE
CERTIFICATE LRQ 0959129/D SCHEDULE**

**In accordance with the requirements of the Medical Devices
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**Sterima N.V.
Zonnekestraat 13,
8501 Bissegem
Belgium**

Scope:

Class I Sterile Devices:

(Only those aspects of manufacture concerned with securing and maintaining sterile conditions)

Sterile Nursing Sets

Sterile Instruments

Sterile Haemodialysis Sets

Sterile Sets for Obstetrical Use

Schedule Issue: 01

Date of Schedule Issue: 16 September 2019

LRQA Notified Body Number 0088



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