EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

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 II 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/B
Original Approval:	28 January 1998
Current Certificate:	01 August 2019
Certificate Expiry:	31 January 2022

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 0959129/B SCHEDULE

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

Sterima N.V.
Zonnekestraat 13,
8501 Bissegem
Belgium

Scope:
Design and manufacturing of haemodialysis solution concentrates

Class IIb Products
Concentrates for Haemodialysis

Schedule Issue: 01

Date of Schedule Issue: 01 August 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited