

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:

Medimark Scientific Limited
4 East Point, Seal High Street,
Sevenoaks, Kent TN15 0EG
United Kingdom

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 4008308/B

Original Approval: 11 February 2014

Current Certificate: 08 July 2019

Certificate Expiry: 30 September 2020

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 4008308/B SCHEDULE

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Medimark Scientific Limited 4 East Point, Seal High Street, Sevenoaks, Kent TN15 0EG United Kingdom

<u>Disinfectant for Medical Devices:</u> Class Ila Products – Non Invasive Devices

Chemgene HLD4H Concentrate
Chemgene HLD4H Ready to use spray
Chemgene HLD4H Wipes
Chemgene HOCL2000 Trigger Spray
Trionic D Concentrate
Trionic D Spray
Troinic D Disinfection Wipes
SOLO Disinfecting Wipes

Class Ilb Products – Invasive Devices

Reprodis HLD4I Chemgene HLD4I Ready to use wipes

Schedule Issue: 03

Date of Schedule Issue: 08 July 2019

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