NSAI

Certificate of Registration
of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

GAMA Healthcare Ltd
The Maylands Building
Maylands Avenue
Hemel Hempstead Industrial Park
Hemel Hempstead, Herts, HP2 7TG
United Kingdom

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design, Manufacture and Distribution of Medical Wipes and Disinfecting Sprays for Disinfecting Non-Invasive Medical Devices.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.8195)

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Caroline Dore Geraghty
Director of Medical Devices/Head of Notified Body

Certificate Number: MD19.8195
Certification Granted: 09 January 2019
Effective Date: 09 January 2022
Expiry Date: 08 January 2025

Annex to Certificate Number: MD19.8195

Scope of Registration:

The Design, Manufacture and Distribution of Medical Wipes and Disinfecting Sprays for Disinfecting Non-Invasive Medical Devices.

Activity	Location
Headquarters, Administration, Manufacturing, Distribution	GAMA Healthcare Ltd The Maylands Building Maylands Avenue Hemel Hempstead Industrial Park Hemel Hempstead, Herts, HP2 7TG United Kingdom File No.: MD19.8195
Administration, Design	GAMA Healthcare Ltd Fellows Research Centre, North Dean Business Park, Stainland Road, Greetland, Halifax HX4 8LR United Kingdom File No.: MD19.8195/A

Verified by:
Operations Manager