

# **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

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

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



All valid certifications are listed on NSAI's website - <u>www.nsai.ie</u>.

The continued validity of this certificate may be verified under "Certified Company Search"

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### 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

File No.: MD19.8195/A

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

Verified by: Operations Manager