



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 Patient Isolation Systems and 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:
Kevin Mullaney
Director of Certification

Certificate Number: MD19.8195

Certification Granted: 09 January 2019

Effective Date: 09 January 2025

Expiry Date: 08 January 2028



NSAI (National Standards Authority of Ireland), 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800
NSAI Inc. 20 Trafalgar Square, Suite 603, Nashua, New Hampshire, USA T +1 603 882 4412



Annex to Certificate Number: MD19.8195

Scope of Registration:

The Design, Manufacture and Distribution of Patient Isolation Systems and 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:
Director of Certification