EU Quality Management System Certificate

Medical Device Regulation 2017/745

The National Standards Authority of Ireland as a duly designated Notified Body, (identification number 0050) for the purposes of the European Union under MDR 2017/745

APPROVES THE QUALITY MANAGEMENT SYSTEM APPLIED BY

GAMA Healthcare Ltd
The Maylands Building
Maylands Avenue
Hemel Hempstead,
Hertfordshire HP2 7TG
United Kingdom

Manufacturer SRN:	GB-MF-0000008527
Authorised Representative Name and Address:	Emergo Europe, Westervoortsedijk 60 6827 AT Arnhem The Netherlands
Device Group:	Clinell Universal Wipes and Spray
Risk Class:	IIa

Conclusion: Quality Management System complies with the requirements of Annex IX, Chapter I & III of MDR 2017/745. The use of the NSAI Notified Body Identification Number 0050 in conjunction with CE Marking of Conformance for this product is hereby authorised.

Product Certificate Number:	745.084	Re-Issued Date:	N/A
First Issue Date:	25 September 2024	Expiry Date:	24 September 2029
Site Certificate Number:	MD19.8195		

Signed: Pamela Burdette Miller

Approved by:
Pamela Burdette Miller
European Medical Device Operations Manager

CONDITIONS AND LIMITATIONS: This certificate remains valid on condition that the Approved Quality Management System is maintained in an adequate and efficacious manner in line with the requirements of the Regulation. This certificate is based on examination of identified relevant CS, harmonised standards, test reports and audit reports maintained on file with NSAI. Information on examination and tests as per Annex XII, section 10, is available on request. Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI. Substantial Changes to the QMS or the product range covered must receive further approval from NSAI.

The validity of this certificate depends on conditions and/or is limited to the following: N/A

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Appendix I			
Certificate History			
Product Certificate Number	Date of Issue	Type of Change *[supplemented, modified or re-issued]*	Details of Change
N/A	N/A	*N/A*	N/A