

Certificate Of Compliance

Geotek Global Certification Pvt. Ltd.

Applicant : Aureole Pharma Pvt. Ltd.

HO Address : Plot No. B - 61, Malegaon MIDC, Taluka Sinnar, District Nashik 422113, Maharashtra, India

Manufacturer : **Aureole Pharma Pvt. Ltd.**

Address : Plot No. B - 61, Malegaon MIDC, Taluka Sinnar, District Nashik 422113, Maharashtra, India

CE Mark Directive : 2007/47/EC as amended by Regulation (EU) 2017/745 (MDR)

Certificate No. : 23GGCSIN 300393 Rev. No. : 00

Certification Date : 12th January 2024 Valid Till : 11th January 2029

Products Covered : Humidity Chamber, Walk in Humidity Chamber, Walk in BOD Incubator, BOD Incubator, Walk in Cold Chamber, Cold Chamber, Deep Freezer, Walk in Deep Freezer, Water Bath, Muffle Furnace, Bacteriological Incubator, Hot Air Oven, Vacuum Oven, Photostability Chamber

Standards Referred : BS EN IEC 60068-3-6:2018 Environmental testing - Supporting documentation and guidance. Confirmation of the performance of temperature/ humidity chambers
BS EN IEC 60068-3-4:2023 - TC Environmental testing - Supporting documentation and guidance. Damp heat tests
ASTM E595-15(2021) Standard Test Method for Total Mass Loss and Collected Volatile Condensable Materials from Outgassing in a Vacuum Environment
ISO 14971:2019 Medical devices - Application of risk management to medical devices
BS EN ISO 20417:2021 Medical devices. Information to be supplied by the manufacturer
BS EN 60601-1:2006+A2:2021 Medical electrical equipment - General requirements for basic safety and essential performance
BS EN 60601-1-8:2007+A11:2017 Medical electrical equipment. Part 1-8: General requirements for basic safety and essential performance
IEC/TR 62366-2:2016 Medical devices - Part 2: Guidance on the application of usability engineering to medical devices



Chief Executive Officer

Geotek Global Certification Pvt. Ltd.

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Geotek Global Certification Pvt. Ltd. is accredited by International Management Accreditation Board (Singapore)
51, Goldhill Plaza, #07-10/11, Singapore 308900



The CE mark as shown above can be used under the responsibility of the manufacturer after completion of an EC Declaration Of Conformity and compliance with all relevant EC Directives. Geotek Global Certification Pvt. Ltd. is non-notified body therefore this certificate falls under non notified certification. The continual validity of the certificate is conditional to compliance with the terms and the conditions of Geotek Global Certification Pvt. Ltd. Validity of the certificate may be verified on following websites : www.geotek.co.in and accreditation body's website : www.imach.com