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# Certificate of Compliance

## CE

This is to certify that the technical documentation/inspection/test results comply with the requirement of Medical Device Directive 93/42/EEC manufactured by:

**NAME: HALENESS DISPOSABLE PRODUCTS LLP**

**ADDRESS: INDUSTRIAL GROWTH CENTRE, 3RD PHASE, 2 NO. JAMBHARI MOUZA BONGAON CHAYGAON, KAMRUP, ASSAM- 781141, INDIA**

**PRODUCTS: DESIGN & DEVELOPMENT, MANUFACTURING & SALES OF STERILE & NONSTERILE SINGLE USE SYRINGES WITH & WITHOUT NEEDLE & HYPODERMIC NEEDLE**

### COMPLIES WITH THE REQUIREMENTS APPLICABLE TO IT

The Certification Body has performed an independent audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the Medical Device Directive Applicable IEC 60601 series standard 93/42/EEC.

### THIS CERTIFICATE IS ISSUED UNDER THE FOLLOWING CONDITIONS:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
5. 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. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

### Certification Calendar:

Client Id: 41052

Certificate No: INCE/AS-42271/0523

Initial Registered Date: 26.05.2023

Date of Expiry: 25.05.2026

1<sup>st</sup> Surv. Due: 25.05.2024

Issuance Date: 26.05.2023

2<sup>nd</sup> Surv. Due: 25.05.2025



Authorized Signatory