Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of Directive EU MDR 2017/745.

Manufacturer

Name : **STERIX GLOBAL PRIVATE LIMITED**

Address : **Registered Office: Flat No. 502, Tower No. 12, SunBreeze 1, Faizabad Road, BBD Green City, Lucknow- 226028, U.P. (India)**
Factory Address: Gata No. 22, Dewa Road, Palta, Dewa, Barabanki- 225301, U.P. (India)

Product : **Disposable Hypodermic Syringe (Needle & Without Needle), Auto Disable Sterile Hypodermic Syringe With Needle, Disposable Hypodermic Needles, Intravenous Cannula, Infusion Set, Blood Transfusion Set, Scalp Vein Set, 3-Way Stop Cock, Ryle's Tube, Yankauer Suction Set, Extension Tube, Blood Collection Needle, Umbilical Cord Clamp, Infant Feeding Tube, Spinal Needle & Foley Catheter**

The Certification body has performed an 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 Directive EU MDR 2017/745.

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 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

Date Of Registration: 19/08/2026 **2nd Surveillance Due: 18/08/2028**
1st Surveillance Due: 18/08/2027 **Recertification Due: 18/08/2029**

CERTIFICATE No:- CE-1438

To Verify this certificate please visit at www.arcadecert.co.uk

CE

AMC

daniel payden
Authorised Signatory

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