

CERTIFICATE

Of Compliance

This is to certify that the technical documentation has been independently assessed and compliant with the requirements of Medical Device Regulation (EU) 2017/745 (earlier legislation Council Directive 93/42/EEC), LVD directive 2014/35/EU.

Manufacturer

Name : M/S ADVANCE BIOTECH SOLUTIONS INDIA PVT. LTD.

Address : 311, VARDHMAN KEY POINT PLAZA, PLOT NO.1, LSC,

DWARKA, SECTOR - 6, NEW DELHI - 110075, INDIA

Brand Name : POLE (STAR SYMBOL) ADVANCE

Product Details : ULTRA LOW TEMPERATURE LABORATORY DEEP FREEZER

Models : EXTERNAL SINGLE DOOR MODELS: PSA-86SDU125, PSA-86SDU350, PSA-86SDU425, PSA-86SDU500, PSA-86SDU525,

PSA-86SDU575, PSA-86SDU600, PSA-86SDU650, PSA-86SDU675, PSA-86SDU700, PSA-86SDU775, PSA-86SDU800, PSA-86SDU875,

PSA-86SDU925, PSA-86SDU975.

EXTERNAL DOUBLE DOOR MODELS: PSA-86DDU500,

PSA-86DDU650, PSA-86DDU750, PSA-86DDU850, PSA-86DDU950

Applicable Standard : Medical Device Regulation (EU) 2017/745 (earlier

legislation Council Directive 93/42/EEC), LVD Directive

2014/35/EU and IEC 61010-1:2010

This certificate refers to the information examined and read with manufacturer's declaration of conformity. Further, the product liability rests with the manufacturer or his representative in accordance with the Medical Device Regulation (EU) 2017/745 (earlier legislation Council Directive 93/42/EEC), LVD directive 2014/35/EU The CE Mark as shown below can be used, under the responsibility of manufacturer, after completion of a CE Declaration of conformity and compliance with the relevant CE Directives.

Certificate No.: SPC24C9782

Date of Initial Registration: 24-12-2024
1st Surveillance audit on or before: 23-12-2025
2nd Surveillance audit on or before: 23-12-2026
Date of Recertification: 24-12-2027

Authorised Signatory

SP Certification Limited

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Verify Certificates

Accredited by Accreditation Forum of International Standards [AFIST (UK) LTD.]

9, Park View Road, Leeds, LS4 2LG, United Kingdom (UK), Email: info@afist.org, Website: www.afist.org
The approval is subject to the company maintaining its system to the required standards, which will be monitored by SPC.
The Certificate remains the property of SPC and must be returned on request.

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