



CERTIFICATE

This is to certify that

Confirms that the products of class I according to the Medical Council Directive 93/42/EEC of June 1993

Certificate Number: CE-4379

Manufacturer

Name : Advance Mediplus Pvt. Ltd.
Address : B-71/1B, 2nd Floor, Lawrence Road Industrial Area, Delhi-110035, India
Products : Medical & Surgical Equipments
(more detail as per appendix page-6)

Models : As per appendix page-I

The manufacturer's technical documentation as required for class I device has been reviewed and found to comply with the requirements any significant changes in the design or construction of the product, not agreed upon by us, this declaration will lose its validity.

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

Date of initial registration: 18th March 2020
Date of this Certificate: 03RD March 2021

Certificate Expiry: 17th March 2022
Recertification Due: 17th March 2023

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Head of Certification

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DBS CERTIFICATIONS PVT. LTD.

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CERTIFICATE

Certificate of Compliance

Appendix-I

Appendix to Certificate no. :

CE-4379

Manufacturer :

Advance Mediplus Pvt. Ltd.

Address :

B-71/1B, 2nd Floor, Lawrence Road Industrial
Area, Delhi-110035, India

This certificate referred to above covers the following products like:

PRODUCTS & MODELS:-

1. Radiant Heat Warmer
2. Phototherapy Systems
3. Bubble C-pap / Flow Controlled Nasal C-Pap
4. Oxygen Concentrator
5. Infant incubator/Transport Incubator
6. Baby Bassinet/Infant Care Trolley
7. Neonatal Resuscitation Unit
8. Resuscitation Kit & Accessories
9. Oxygen Hood
10. Infantometer
11. Weighing Scale
12. Airways (All Sizes)
13. Syringe Pump
14. Infusion Pump
15. Foetal Monitor
16. Hospital Furniture/O.T. Light
17. Cold Light Source
18. Fibre Optic Cable
19. Vein Locator/Viewer
20. Silicon Resuscitator(All Sizes)

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Appendix-II

Appendix to Certificate no. :

CE-4379

Manufacturer :

Advance Mediplus Pvt. Ltd.

Address :

B-71/1B, 2nd Floor, Lawrence Road Industrial
Area, Delhi-110035, India

This certificate referred to above covers the following products like:

PRODUCTS & MODELS:-

21. Silicon Mask (All Sizes)
22. T.P. Resuscitator
23. Centrifuge
24. Bilirubinometer Meter/Jaundice Meter
25. OPEN CARE SYSTEM/INFANT WARMER/ RADIANT HEAT WARMER WITH T-PIECE
RESUSCITATOR AND BLENDER OR AIR OXYGEN MIXER
 - IW5000
 - IW5100
26. OPEN CARE SYSTEM/INFANT WARMER /RADIANT HEAT WARMER
 - IW1000
 - IW1001
 - IW1100
 - IW1101
27. Radiant Heat Warmer/Infant Warmer/Neonatal Warmer
 - IW- 1000
 - IW- 1001
 - IW- 1002
 - IW- 1003
 - IW- 1004
 - IW- 1005
 - IW- 1100
 - IW- 1101

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Appendix-III

Appendix to Certificate no. :

CE-4379

Manufacturer :

Advance Mediplus Pvt. Ltd.

Address :

B-71/1B, 2nd Floor, Lawrence Road Industrial
Area, Delhi-110035, India

This certificate referred to above covers the following products like:

PRODUCTS & MODELS:-

- IW- 1102
 - IW- 1103
 - IW- 1104
 - IW- 1105
 - IW- 5000
 - IW- 5100
 - IW- 5200
 - NWPT
 - NWPT 1100/1000
 - NWPT 1101/1001
28. Open Care System/Infant Warmer/Radiant Heat Warmer With T. Piece Resuscitator and Blender or Air-Oxygen Mixer without Compressor
- OCS- 1001
 - OCS-1101
 - OCS- 5000
 - OCS- 5100
29. Neonatal Warmer with Pulse Oximeter
- NWP 1001
 - NWP 1101
 - NWP 5000
 - NWP 5100

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Appendix-IV

Appendix to Certificate no. :

CE-4379

Manufacturer :

Advance Mediplus Pvt. Ltd.

Address :

B-71/1B, 2nd Floor, Lawrence Road Industrial
Area, Delhi-110035, India

This certificate referred to above covers the following products like:

PRODUCTS & MODELS:-

30. Phototherapy System

- IP- 200
- IP- 210
- IP- 220
- IP- 230
- PTE
- PTE- 210
- PTE- 220
- PTE- 230

31. Bubble CPAP/Flow Controlled Nasal CPAP

- CPAP- 1000
- CPAP- 1100
- CPAP- 2000
- CPAP- 2100

32. Oxygen Concentrator

- OCSF
- OCDF

33. Infant Incubator

- INC- 1000
- INC- 2000

34. Transport Incubator

- TINC- 1000
- TINC- 2000

35. Baby Bassinet/Infant Care Trolley

- ICT- 6001

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Appendix-V

Appendix to Certificate no. :

CE-4379

Manufacturer :

Advance Mediplus Pvt. Ltd.

Address :

B-71/1B, 2nd Floor, Lawrence Road Industrial
Area, Delhi-110035, India

This certificate referred to above covers the following products like:

PRODUCTS & MODELS:-

- 36. Neonatal Resuscitation Unit
 - NRU- 1000
 - NRU- 1001
 - NRU- 1100
 - NRU- 1101
 - NRU- 5000
 - NRU- 5100
- 37. Resuscitation Kit & Accessories
 - RSKN
 - RSKP
 - RSKA
- 38. Oxygen Hood
 - OHDS
 - OHDM
- 39. Infantometer
- 40. Weighing Scale
 - NWS-5/10/20
 - MWS-200
 - AWS- 200
- 41. Airways
 - AWN
 - AWA
- 42. Syringe Pump
- 43. Infusion Pump

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Appendix-VI

Appendix to Certificate no. :

CE-4379

Manufacturer :

Advance Mediplus Pvt. Ltd.

Address :

B-71/1B, 2nd Floor, Lawrence Road Industrial
Area, Delhi-110035, India

This certificate referred to above covers the following products like:

PRODUCTS & MODELS:-

- 44. Fetal Monitor/CTG Machine
- 45. Hospital Furniture/O.T.Light
- 46. Cold Light Source
- 47. Fibre Optic Cable
- 48. Vein Locator/Viewer
 - VV
- 49. Silicon Resuscitator(All Sizes)
 - MRN- 250 ML
 - MRP- 500 ML
 - MRA- 1600 ML
- 50. T. P. Resuscitator/Baby Puff/Resipuff
 - TP- 1050
- 51. Centrifuge
- 52. Bilirubinometer Meter/Jaundice Meter
- 53. Humidifier
 - HU- 310
- 54. Blender
 - OBS- 1000
 - OBD- 1100

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