

6<sup>th</sup> January, 2021

## Authorizations / Certifications

***Apollo Computing Laboratories (P) Ltd., (ACL)*** is a premier Leading Aerospace Company involved in the Design Development and Production of Major On-Board Electronic Systems for the Strategic National Defence Programmes like AGNI Series of Missiles, LCA / Tejas Military Fighter Aircraft etc.

***SwasthVayu - The Non Invasive Ventilator Technology is Transferred to ACL*** by National Aerospace Laboratories (NAL), a constituent of the Council of Scientific and Industrial Research (CSIR), the only Indian Government Aerospace Research & Development Laboratory in the Country's Civilian Sector.

The following authorizations/certifications are in place for SwasthVayu – Non Invasive Ventilator through CSIR-NAL.

1. Government of India, Ministry of Health and Family Welfare Authorization letter No: Z-28015/146/2020-EMR dated 24th December, 2020
2. License Agreement between CSIR-NAL & ACL dated 20<sup>th</sup> May, 2020 for Technology Transfer of SwasthVayu – Non Invasive Ventilator.
3. CSIR-NAL Publication No.: 0304214-00 & Test reports of:
  - Electrical Safety Report as per IEC 60601-1, IEC 62353
  - Calibration Report as per IEC 17025:2005
  - BIO Compatibility report as per ISO10993-5
  - SwasthVayu – Non Invasive Ventilator has been certified by international agency TÜV Rheinland for IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012
4. ACL's Manufactured SwasthVayu has got the following Certifications on Apollo Computing Laboratories (P) Ltd.
  - The SwasthVayu is certified for IEC 60601-1:2005, COR IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint) by International Agency TUV.
  - The SwasthVayu is also certified for Electrical Safety as per IEC 62353 and BiPAP Performance Calibration as per ISO/IEC 17025:2005 by Transcaal Engineers, a Test laboratory accredited by NABL.

- ACL's SwasthVayu is certified for ISO 13485:2016 (MDQMS- Medical Devices Quality Management System).
- ACL's SwasthVayu is also certified to be compliant with the requirements of ISO 10933-12:2012 (Biological evaluation of medical devices — Part 12: Sample preparation and reference materials) & ISO 10993-5:2009 (Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity)
- ACL's SwasthVayu is certified for Compliance with ROHS directive 2002/95/EC, Directive 93/42/EEC: Medical Devices on the restriction of use of certain Hazardous Substances [Lead (Pb), Mercury (Hg), Cadmium (Cd), Hexavalent Chromium (Cr6+), Polybrominated biphenyls (PBBs) and Polybrominated Diphenyl ethers (PBDEs)] in Electrical and Electronic Equipments by Optimum Certifications Inc., a Test Laboratory accredited by Scotland Accreditation Forum, Scotland.
- ACL's SwasthVayu is also certified for Compliance with meeting the requirements of Directive 93/42/EEC: Medical Devices by Optimum Certifications Inc., a Test Laboratory accredited by a Laboratory accredited by Scotland Accreditation Forum, Scotland.

Sincerely,

**For Apollo Computing Laboratories (P) Ltd.**



**B. Jaipal Reddy**  
**Managing Director**