EC Certificate Full Quality Assurance System: Certificate IN19/818843685

The management system of

Alan Electronic Systems Pvt. Ltd.

Plot No. F-75, MIDC, Additional Ambernath Industrial Area, Anand Nagar,
Jambivali, Ambernath (East) - 421506, Dist. Thane, Maharashtra, India

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Electro Surgical Generators with Foot switch & Patient Plate for Cutting, Coagulation, resection of tissues and for sealing of vessels. [Models: ELSY-360 series (M+, D+, L+), Lite series (A-Lite, E-Lite), Touch series 5" (Combi-Max APC, Combi-Max, Combi-Plus, Combi, Plasma-Plus, Plasma, Alligature, Alligature-E, M+Touch), Touch series 7" Combi Max (MBAVP, MBAVX, MBAXP, MBAXX, MBXVP, MBXVX, MBXXP, MBXXX as M+ Touch)]

CO2 Insufflator to inflate the patient's abdomen during surgery [Models: ALINCO-30, ALINCO-45, ALINCO-60].

This certificate is valid from 16 December 2019 until 10 November 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 10 November 2015
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered IN/MUM 235613

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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27/09/2023

Alan Electronic SystemsPvt. Ltd.
Plot No. F-75, MIDC,
Additional Ambernath Industrial Area, Anand Nagar,
Jambivali, Ambernath (East) - 421506,
Dist. Thane, Maharashtra, India

Confirmation Letter Reference: CLNB1639INMUM235613

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Alan Electronic Systems Pvt. Ltd.
Plot No. F-75, MIDC,
Additional Ambernath Industrial Area, Anand Nagar,
Jambivali, Ambernath (East) - 421506, Dist. Thane, Maharashtra, India
SRN Number: IN-MF-000007438

EU REP:
MED Devices Lifesciences B.V
Keizersgracht 482, 1017 EG Amsterdam, The Netherlands
SRN No.: NL-AR-000 000 594

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

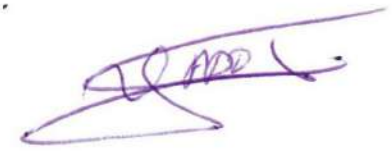
- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry.
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

SGS NB1639 Confirmation letter Regulation (EU) 2023/607

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,



pp [Jérôme JADOT]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

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Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Electro Surgical Generators with Foot switch & Patient Plate for Cutting, Coagulation, resection of tissues and for sealing of vessels. [Models: ELSY-360 series (M+, D+, L+), Lite series (A-Lite, E-Lite), Touch series 5" (Combi-Max APC, Combi-Max, Com bi-Plus, Combi, Plasma-Plus, Plasma, Alligature, Alligature-E, M+Touch), Touch series 7" Combi Max (MBAVP, MBAVX, MBAXP, MBAXX, MBXVP, MBXVX, MBXXP, MBXXX as M+ Touch)]	Class IIb	N/A	IN19/ 818843685 issue-1; NB1639

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CO2 Insufflator to inflate the patient's abdomen during surgery [Models : ALINCO-30, ALINCO-45, ALINCO-60].	Class IIb	N/A	IN19/ 818843685 issue-1; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/09/27	Version 1	Initial issue

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607