



**Amtronix** PTY  LIMITED

**Amtronix - breaking the sound barrier**

info@amtronix.co.za

www.amtronix.co.za

Reg No. 1977/001577/07

P O Box 26318  
East Rand 1462  
Gauteng, South Africa

Tel: 0861 Amtronix  
0861 268 766  
+27 11 894 4632  
Fax: +27 11 604-4319

## Sole provider / Supplier confirmation

Dear Valued Client,

Amtronix management would like to reiterate the following regarding our products and services:

Amtronix has **not** authorized or certified any third parties to perform maintenance, repairs, calibrations, and servicing of any equipment supplied by Amtronix.

Amtronix personnel are trained and certified in the maintenance, repairs, calibrations, and servicing of the devices and possess the requisite certification issued by the Original Equipment Manufacturer (OEM).

All Amtronix calibration equipment is **SANAS certified** and complies to the **SANS** requirements. Certificates are available on request.

All the devices that Amtronix supply into the market are **CE certified** and are registered with the **Radiation Directorate**, ensuring adherence to the safety and legal compliance requirements applicable to the devices. Certificate is available on request.

Furthermore, Amtronix is registered with the **SAHPRA** (South Africa Health Products Regulatory Authority) (the registration of all company for manufacturers, wholesalers, or distributors of medical devices is a requirement by law). This registration is **mandatory** for any South African company that supplies any medical equipment. Certificate is available on request.

To check if a company is registered with SAHPRA, kindly follow the link below:

<https://www.sahpra.org.za/medical-devices-licences-issued/>.

Amtronix has spent time and effort in establishing a Quality Management System **QMS** that ensures that the products and services that Amtronix offers are of an International Standard. This has culminated in Amtronix being certified according to **ISO 13485:2016** (Medical devices – quality management systems – requirements for regulatory purposes). Certificate is available on request.