



LUX | TSI

SIRIM LCA Seminar on Global Market Access (GMA) Testing Capabilities and Technical Services for E&E Equipment in SIRIM Penang



January 2016

Contents



With the rapid changes to electrical and electronic products and with beginning of the <u>internet of</u> things, the traditional supply chain is being increasingly disrupted with many new suppliers and products lacking proven track records of reliability and performance.

Today we will explore the routes to compliance to the key regulatory requirements to take products from local markets into global markets.

Lux Group of Companies



Delivering excellence in Testing, Consultancy and Certification world wide





The VAULT Knowledge Base



JV with ESC (Malaysia/A SEAN Region) Consultancy Services



Global
Consultancy
Company –
E&E,
Medical and
Machinery
focus



LUX | UK

UK/Northern
Europe
Testing
Laboratory
Est 2010



LUX | CEE

Central &
Eastern Europe
Partnership
(ex TUV GM)



LUX | CSC

Global Consultancy (Cyber Security Compliance & Certification)

An Example of the Disruptive Changes going on in our world

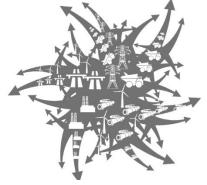


The global lighting industry is going through a period of disruptive change!









Traditional lighting...

Glass and Gas

Dominated by large established players

Inefficient, Inflexible

has gone digital...

LED's are semiconductor electronics

Huge variations in quality New players

growth is accelerating

Philips forecasts the LED market to grow from 15% to 80% by 2020

2015 growth has already exceeded forecasts

resulting in chaos!

Confusing standards
Changing regulations
Complex supply chain
Lack of trust in data

Different rules

Different players

Different pricing

Different qualities

Huge variations in quality

Confusing standards

Changing regulations

No single certification authority

Suppliers

Manufacturers

Designers

Retailers &

Consumers

are confused



LUX | LCA

There is a large and growing need for honest, trustable advice, certification and validation of all this confusing data for the global marketplace





All this confusion exists without the new wave called the

"Internet of Things (IoT)"

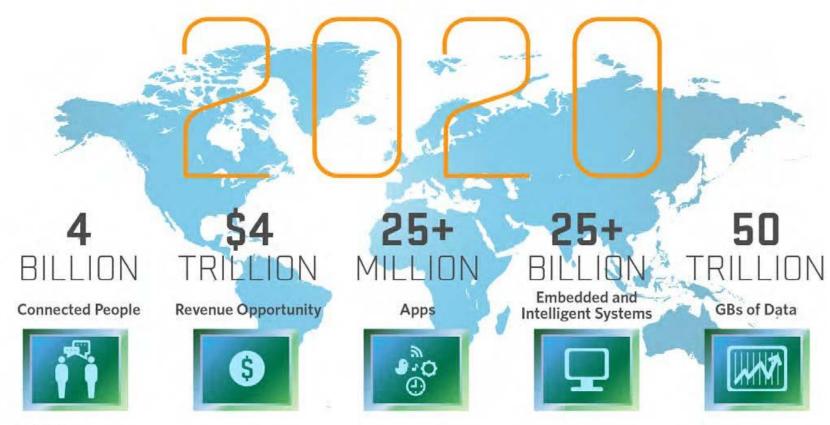
Very new Very exciting.... Very concerning

Everything connected lacking proper standardisation and regulation

Software security will become very important in this new world

IoT World





Source: Mario Morales, IDC

2016 LUX-TSI Limited

Summary of Key Activities of LCA for E&E/Medical Equipment



CE Marking guidance and management

Perform Technical File Reviews

Specialised Protocol Services

Gap Analysis when standards or regulations change - Standard update service

Support you obtain the approvals, permits, import certificates, export certificates and licenses that you need for your products so that you can reach new markets

Worldwide Authorised Representative Services (via LUX-IEC) via our network of AR providers – can also support local distribution requirements – particularly for medical products.

Factory Inspections/Audits

Pre Shipment Audits/Inspections

Technical Support in guiding through standards

Oversee third party compliance testing – liaising closely with the requested lab

CE/UL/IEC Seminars for international markets

Oversee technical issues consultation with manufacturers

Introduction and communication with Notified Bodies

www.lux-iec.com contains more information for medical devices





© 2016 LUX-TSI Limited

The World Standards and Certification Systems



Key International Standards and Certification Setting Bodies:

IEC IEC safety and performance standards

CISPR radio interference (EMC)

CEN European translation of IEC stndards

ICNIRP Non-ionising radiation (i.e. light, UV, IR, Microwave, Radio)

CIE Photometry and Lighting

IESNA Lighting

ANSI/UL US Standards for Safety and Performance

JES/JEDEC/MIL Environmental/Reliability/Lifetest/Mechanical/

CSA Canadian Standards for Safety

PSF Japan

FCC Federal Communications Commission - radio, television,

wire, satellite, and cable communications in USA

Zhaga - proprietary groups

Wi-Fi

Zigbee

Bluetooth















Key Safety Compliance Routes – 2 worlds



Europe and Rest of World	North America, Mexico
IEC Derived Standards	ANSI/UL Approved Standards
IECEE CB Scheme is most widely accepted	

National and Regional Deviations Important (e.g. EN, SASO, AZ/NZS, PSE)

EN useful for Europe – based on IEC

Technical File Essential



Critical Components Essential

Higher End Markets demand Accredited Test Reports from Independent Third Party Labs

Must be approved by Authority Having **Jurisdiction**

Technical File Essential

Critical Component Essential

National Recognised Testing Laboratory - NRTL (i.e. must be from Accredited Testing Laboratory)

2016 LUX-TSI Limited

E&E Equipment classified by IECEE





- IT and office equipment
- **Audio Visual**
- Household and similar equipment
- Measurement, Control and Lab Equipment
- **Medical Devices**
- Lighting
- Toys
- **Batteries**
- Low voltage, high power switching equipment
- Safety Transformers
- **Cables and Cords**
- **Industrial Automation**
- **Photovoltaics**
- Electronics for entertainment

				ELVH	Electric Vehicles	60783, 60785, 61851,
				ELVII	Electric verificies	<u>62196, 62660,</u>
	IEC Standards					60034, 60118, 60204,
	IEC Starr	aaras				<u>60255, 60533, 60601,</u>
						<u>60728, 60870, 60945,</u>
	Catagories	Products	IEC Ctandards			60947, 60974, 61000,
	Categories	Products	IEC Standards			61131, 61204, 61326,
			<u>60086, 60095, 60099,</u>			<u>61543, 61547, 61800,</u>
			<u>60254, 60571, 60622,</u>			<u>61812, 62003, 62040,</u>
			<u>60623, 60896, 60952,</u>		Electromagnetic	<u>62041, 62052, 62053,</u>
	BATT	Batteries	61133, 61809, 61951,	EMC	Compatability	<u>62054, 62153, 62236,</u>
			<u>61960, 61982, 62133,</u>		Compacability	62311, 62493, CISPR 11,
			<u>62257, 62259, 62281,</u>			<u>CISPR 12, CISPR 13,</u>
			62282, 62660,			<u>CISPR 14, CISPR 15,</u>
			60227, 60245, 60502,			CISPR 16, CISPR 20,
	CABL	Cables and Cords	60702, 60800, 60840,			CISPR 22, CISPR 24,
	CADL	Capies and Corus	62067, 62275, 62821,			CISPR 25, CISPR 32,
						CISPR 61000, CISPR/TR
		Capacitors as	<u>60252, 60384, 60831,</u>			<u>16,</u>
	CAP	components	<u>60939, 61048, 61049,</u>			60204, 60311, 60312,
		components	<u>61071, 61881,</u>			60335, 60342, 60350,
		Switches for			Household and similar	60436, 60456, 60530,
		appliances and	60255, 60691, 60730,	HOUS		60580, 60661, 60704,
i	CONT	automatic controls for	60934, 61095, 61508,		equipment	60705, 60967, 61011,
İ		electrical household	61810,			61121, 61591, 61770,
i		appliances	<u>01010,</u>			<u>61817, 62233,</u>
i		иррпинесэ	50004 50000 50044		Hazardous Substances	
			60034, 60299, 60311,	HSTS	Testing Service	<u>62321,</u>
			60312, 60350, 60379,			60034, 60204, 60439,
i			60436, 60442, 60456,	INDA	Industrial Automation	60947, 61010,
i			<u>60496, 60508, 60530,</u>			
			<u>60535, 60619, 60661,</u>			60083, 60309, 60320,
			<u>60665, 60675, 60705,</u>			60364, 60423A, 60423,
73	E3	Energy Efficiency	<u>60879, 60969, 61121,</u>			60614, 60669, 60670,
nited	LJ	LIICIBY LINGICITY	<u>61254, 61309, 61591,</u>			60684, 60799, 60807,
2016 LUX-TSI Limi			<u>61592, 61683, 61817,</u>			<u>60884, 60974, 60998,</u>
<u>S</u>			61855, 61923, 62018 <u>,</u>	INICT	Installation accessories	60999, 61058, 61076,
×			62040, 62075, 62087,	INST	and connection devices	61084, 61210, 61238,
) j			62301, 62473, 62552,			61242, 61316, 61386,
016			62587, 62611, 62612,			61534, 61535, 61537,
© 2(62617, 62623, 62717,		61800, 61950, 61984,	
			<u> </u>			<u>61995, 62080, 62094,</u>

C2102 C210C C2200

			60064, 60081, 60155, 60238, 60357, 60360, 60400, 60432, 60570, 60598, 60838, 60901, 60921, 60923, 60925, 60927, 60929, 60968,	PROT	Installation protective equipment	60099, 60127, 60257, 60269, 60282, 60898, 61008, 61009, 61540, 61643, 62423, 62606, 62640,
	LITE	Luminaires	60969, 61047, 61048, 61049, 61050, 61184, 61195, 61199, 61228, 61347, 61549, 62031, 62035, 62257, 62384, 62471, 62532, 62560, 62612, 62717, 62722, 62776, 62778, 62868,	PV	Photovoltaics	60891, 60904, 61194, 61215, 61345, 61646, 61683, 61702, 61721, 61727, 61730, 61829, 61853, 62093, 62108, 62109, 62116, 62124, 62257, 62446, PVRS 5A, PVRS 7A, PVRS11A, PVRS11, PVRS5, PVRS6A, PVRS6, PVRS7,
	MEAS	Measurement, Control and Laboratory equipment	60044, 60414, 61010, 61131, 61204, 61243, 61557,			60044, 60076, 60704,
	MED	Electrical equipment	10079, 60601, 60613, 60976, 61223, 61676, 62220, 62304,	SAFE	Safety transformers and similar equipment	60742, 61558, 61869, 61980,
		for medical use	62353, 62366, 62462, 62467, 62563, 80601,	TOOL	Portable tools	60745, 61029, 61939, 62841,
nited		IT and office	60950, 61204,	TOYS	Electric Toys	<u>62115,</u>
© 2016 LUX-TSI Limi	OFF	equipment	62040, 62310, 62368, 60158, 60265,	TRON	Electronics, entertainment	60065, 60491, 61204, 61965, 62368,
© 2016 LI	POW	Low voltage, high power switching equipment	60439, 60947, 61439, 61851, 62019, 62026, 62271, 62314			14





Key Questions



- Where do you want to sell your products?
- What does your product do?
- How does it work? (begin to look at the hazards involved)
- Do you have a technical file with key information including data sheets?
- What is the intended use for your products?
- Will it be used indoor/outdoor dry or wet use?
- It is portable or fixed?

European Marks



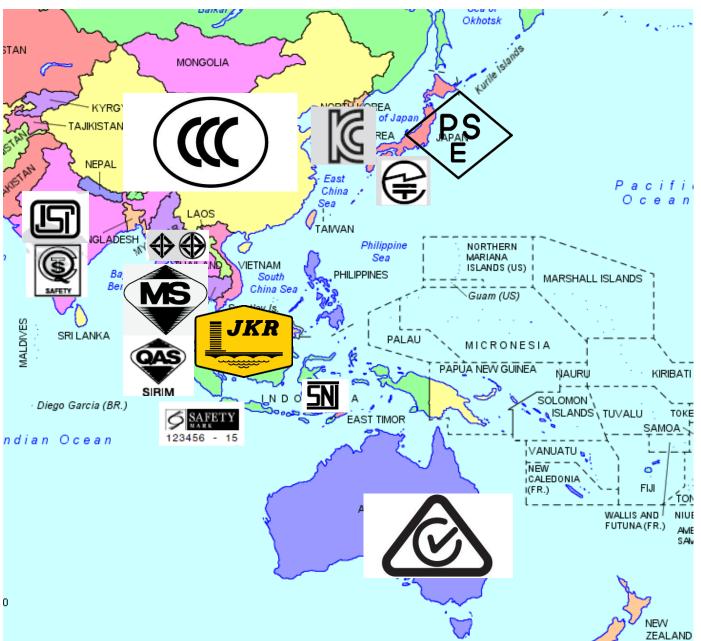






© 2015 LUX-TSI Limited

Asia-Pacific Markets





© 2015 LUX-TSI Limited

North America





Key Technical Compliance Parameters in all markets

Critical

Components



LUX	LCA
-----	-----

Safety	Mechanical	Thermal	Fire
	Electrical	Optical (PhotoBio)	EMF
EMC	Emissions	Immunity	Mains
Wireless	Zigbee	Bluetooth	WIFI
Environmental	RoHS	Recycling	WEEE
Energy Efficiency & Performance	Photometric	Electrical Lifetime	Thermal Environmental
	Reliability	Lifetime	Livitorinieritai

Interoperability and Interchangeability



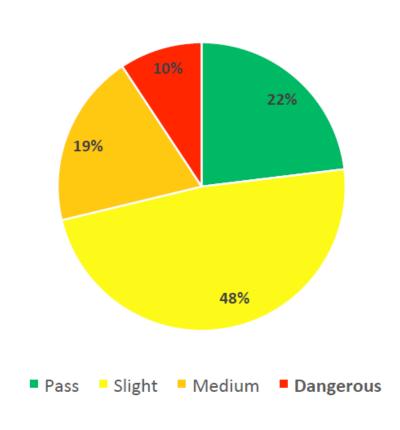


International Federation of Inspection Agencies (IFIA) Study http://www.ifia-federation.org/content/?dl_id=166



22

EU products with CE Markings only (self-declaration)



- Of the 247 samples submitted,
 78% were NOT in compliance with
 EU standards and regulations
- There were 38 instances of safety critical failures which were reported to the local authorities
- Simpler requirements (marking labels and safety instructions) were not met by more than 50% of products evaluated

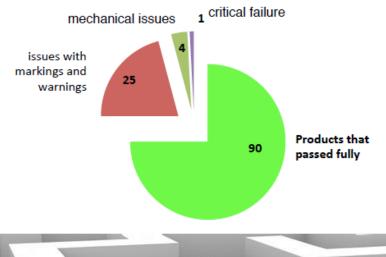
② 2015 LUX-TSI Limited

International Federation of Inspection Agencies (IFIA) Study http://www.ifia-federation.org/content/?dl_id=166



LUX | LCA

EU products certified by accredited, independent third-party bodies





- Of the 120 samples submitted, there was only 1 instance of a safety critical failure, which was reported to the certifier, and then to the manufacturer
- 25% were not in full compliance with EU standards and regulations: marking labels and safety instructions accounted for the vast majority of the issues

8

International Federation of Inspection Agencies (IFIA) Study http://www.ifia-federation.org/content/?dl_id=166

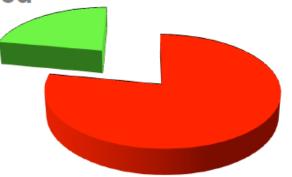


Products where compliance is 'self-declared'

(i.e. NOT reviewed by an independent third-party):

> Non-compliant/faulty products 78%

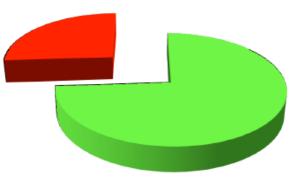
Note: These products are on the market today, and can be purchased and used by any EU consumer



Products where compliance is assessed by an accredited, independent third-party:

> Non-compliant/faulty products 26%

Note: the vast majority were issues related to warnings and labels







CONTENTS



CE Marking and Your Legal Obligations

- What is CE marking?
- What are EU Directives?
- What is Due diligence?
- Declaration of Conformity
- What is a Technical file?
- Placing products on the market
- CE conformity marking

WHAT IS CE MARK?



Any product bearing the **C** mark meets *all* the appropriate provisions of the *relevant* legislation implementing certain European Directives.

CE Marking allows *easy* access to the European Market without adaption or rechecking.

WHAT IS CE MARK

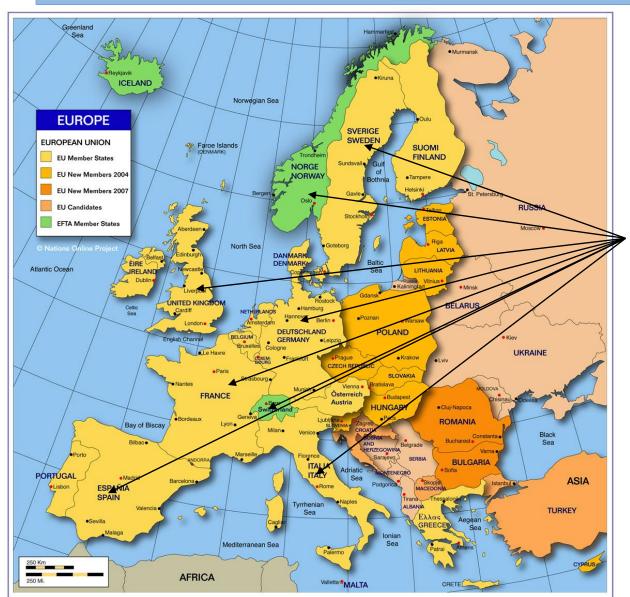


LUX | LCA

- The CE marking symbolises the conformity of the product with the applicable Community requirements imposed on the manufacturer.
- The CE marking affixed to products is a declaration by the person responsible that:
 - the product conforms to all applicable Community provisions, and
 - the appropriate conformity assessment procedures have been completed.
- CE marking does not indicate that a product was made in the EU, but merely states that the product is assessed before being placed on the market and thus satisfies the legislative requirements.
- It is the manufacturer's responsibility to carry out the conformity assessment, to set up the technical file, to issue the EC declaration of conformity and to affix CE marking on a product.

HOW BIG IS EU MARKET





- The EU has the largest GDP in the world.
- Countries in EU have the largest trade market in the world.
- EU E&E market entirely controlled by CE Marking

The Circle of CE



Affix the CE mark and supply instructions

Prepare the Declaration of Conformity

> Maintain the Technical Document File

Identify the Directives

It is the manufacturer's responsibility to carry out the conformity assessment, to set up the technical file, to issue the EC declaration of conformity and to affix CE marking on a product.

Identify whether independent assessment is required Identify the conformity assessment requirements

Identify the Standards

Ensure the Product Complies – Testing



What are EU Directives?



WHAT ARE EU DIRECTIVES?



- "New Approach" Directives (Community Law) set out the essential requirements.
- Written in general terms and must be met before products may be sold in the EU.
- Directives explain how manufacturers are able to demonstrate conformity with the essential requirements.
- European harmonised (EN) standards provide guidance on the detailed technical information enabling manufacturers to meet the essential requirements
- A directive is a legal document. Providing the detail the will of the EU. Very broad and not product specific.
- A standard is product specific and guides the manufacturer through the process and requirements.
- The New Legislative Framework (NLF) imparts new definitions with aim to improve market surveillance and boost the quality of conformity assessments. It also clarifies the use of CE marking and creates a toolbox of measures for use in product legislation.

WHAT ARE EU DIRECTIVES?



There are 21 CE marking Directives

Directive	Amended by	Title of directive
2006/95/EC	2014/35/EU	Low Voltage
87/404/EEC	2014/29/EU	Simple Pressure Vessels
90/488/EEC		
93/68/EEC		
88/378/EE	93/68/EEC	Safety of toys
89/106/EEC	93/68/EEC	Construction products
2004/108/EC	2014/30/EU	Electromagnetic compatibility (EMC)
2006/42/EC		Machinery
89/686/EEC	93/68/EEC	Personal protective equipment (PPE)
	93/95/EEC	
	96/58/EC	
90/384/EEC	2014/31/EU	Non-automatic weighing instruments
93/68/EEC		
90/385/EEC	93/42/EEC	Active implantable medical devices
	93/68/EEC	
	2007/47/EC	
90/396/EEC	93/68/EEC	Appliances burning gaseous fuels

WHAT ARE EU DIRECTIVE



11	IX	$I I C \Delta$

Directive	Amended by	Title of directive
92/42/EEC	93/68/EEC	Efficiency requirements for new hot-water boilers fired with liquid
	2004/8/EC	or gaseous fuels
	2005/32/EC	
93/15/EEC	2014/28/eu	Explosives for civil uses
93/42/EEC	98/79/EC	Medical devices
	2000/70/EC	
	2001/104/EC	
	2007/47/EC	
94/9/EC	2014/34/EU	Equipment for explosive atmospheres (ATEX)
94/25/EC	2003/44/EC	Recreational craft
95/16/EC	2014/33EU	Lifts
97/23/EC		Pressure equipment
98/79/EC		In vitro diagnostic medical devices
1999/5/EC		Radio Equipment and Telecommunications Terminal Equipment
2000/9/EC		Cableway installations designed to carry persons
2004/22/EC	2014/32/EU	Measuring instruments

WHAT ARE EU DIRECTIVE?



The CE marking Directives listed below are the ones that would most typically be applicable to non medical E&E products.

Directive	Title of Directive
2006/95/EC	Low Voltage Directive (LVD)
2004/108/EC	Electromagnetic compatibility (EMC)
1999/5/EC	Radio Equipment and Telecommunications Terminal Equipment
2002/95/EC	Restriction of Hazardous Substances (RoHS)
2002/95/EC	Ecodesign

WHAT ARE EU DIRECTIVE



"Just because a Directive does not call for CE marking does not mean the Directive is not applicable."

Other typically applicable directives:-

Directive	Title of Directive
2001/95/EC	General Product Safety Directive (GPSD)
2012/19/EU	Waste from Electrical and Electronic Equipment (WEEE)
2006/25/EC	Artificial Optical Radiation Directive (AORD)

HOW DOES IT WORK



EU Directives

Sets Overall
Objectives in line
with macro
measures, such
as ecodesign or
LVD

EU Regulations (into National Law)

- Prescribes
 Targeted Levels
 of Performance
 for specific
 Products
- SpecifiesLabellingRequirements

(Harmonised) Standards

- Details how to perform tests to determine performance or ensure safety
- EN standards are preferred





WHAT IS DUE DILIGENCE?



- Knowing what is required
- Demonstrating compliance with applicable Directives through providing evidence – tests according to harmonised standards are the best way
- Declaring that you have met the relevant requirements
- Being properly prepared
 - being able to produce a technical file to back up your declaration
 - ready to defend yourself in court if necessary
 - being confident that your product meets the essential requirements and that is safe and fit for use
 - Key failure points labelling and user instructions.





TECHNICAL FILE



"Technical files are your documented evidence to show that products properly comply with the requirements of the markets in which you sell. Should contain all that is of importance from a regulatory aspect."

- Technical documentation must be such as to enable enforcement authorities to assess the conformity of the electrical equipment to the requirements of the Regulations
- It must cover the design, manufacture and operation of electrical equipment
- It can be the same document as your design file for the equipment
- Most importantly, it forms the basis of your safety case!

TECHNICAL FILE CONTENTS



LUX | LCA

<u>Technical File Structure</u>

CE Conformity

Relevant Directives, Relevant Regulations, Relevant Standards Describe Other Markets

Technical Information

Testing Result, Electrical Safety Testing EMC/EMF Testing, Mechanical Testing (IP, IK etc)

Overview

Product Hierarchy Overview, Product List Nomenclature Product Datasheets

Technical File Structure

Product Information

Maintenance, Installation and User instructions
Product Labels and Markings
Records of any risk assessments and assessments to standards
Warranty Terms and Conditions
WEEE Directive Strategy
Peripherals

Drawings and Documentation

Parts List and Bill of Materials
Drawings
Critical Components and Specification
RoHS Certification and Checklists
Wiring and circuit diagrams





Declaration of Conformity for CE Mark



Each directive has slightly different requirements for the content of its Declaration but some features are common to all:

- Name/address of manufacturer (and of responsible person where applicable)
- Model and/or serial number of equipment
- List of relevant directives
- List of standards used, with dates + amendments
- Declaration statement
- Name and position of person signing
- Signature
- Date
- If a notified body is necessary then this should also be displayed.
- Certain directives have more specific requirements which need to be understood in order to provide compliant documents.

EC Declaration of Conformity

In accordance with EN ISO 17050-1:2004

We Acme Widget Ltd

f Unit 1, Wall Farm, Ind. Est., Walsall, W. Midlands, B1 23B

in accordance with the following Directive(s):

2006/95/EC The Low Voltage Directive

2004/108/EC The Electromagnetic Compatibility Directive

98/37/EC The Machinery Directive

hereby declare that:

Equipment Widget manufacturing machine

Model number Super 77 Serial Number 001236

is in conformity with the applicable requirements of the following documents

Ref. No.	Title		Edition/da
BS EN 746-1	Industrial thermoprocessing equipment. Coindustrial thermoprocessing equipment	mmon safety requirements for	1997
EN 60204-1	Safety of machinery. Electrical equipment requirements	of machines. General	2006
BS EN 61000-6-1	Electromagnetic compatibility (EMC). General residential, commercial and light-industrial		2001
BS EN 61000-6-3	Electromagnetic compatibility (EMC). General and lie		2001

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all applicable Essential Requirements of the Directives.

Signeds



 Name:
 Nigel Watkins

 Position:
 Technical Director

 Walsall
 Walsall

On 1 April 2009







Contact

Dr Gareth Jones
CEO LUX TSI
gjones@lux-tsi.com