

intelesens))

The Complete Electrode Expert & Partner

From concept development to commercial manufacturing



COMPANY OVERVIEW



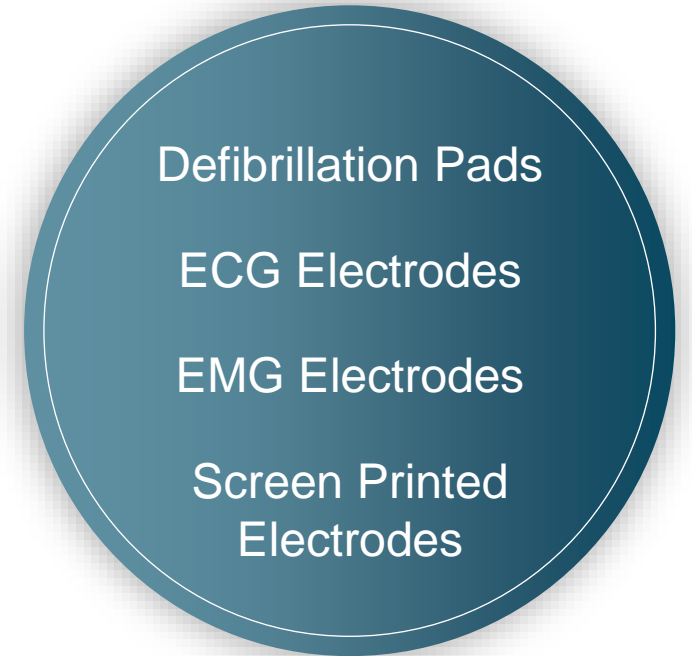
Intelesens began operations in 2000 - a spinout from the Ulster University in Northern Ireland, having specific expertise in the application of sensor technologies



The Company has established a leadership position within the medical sensor industry - Based on its physiological sensor design and development capabilities and unique manufacturing processes for many types of body worn sensors



Intelesens facility includes - R&D, Manufacturing, Logistics and Customer Service



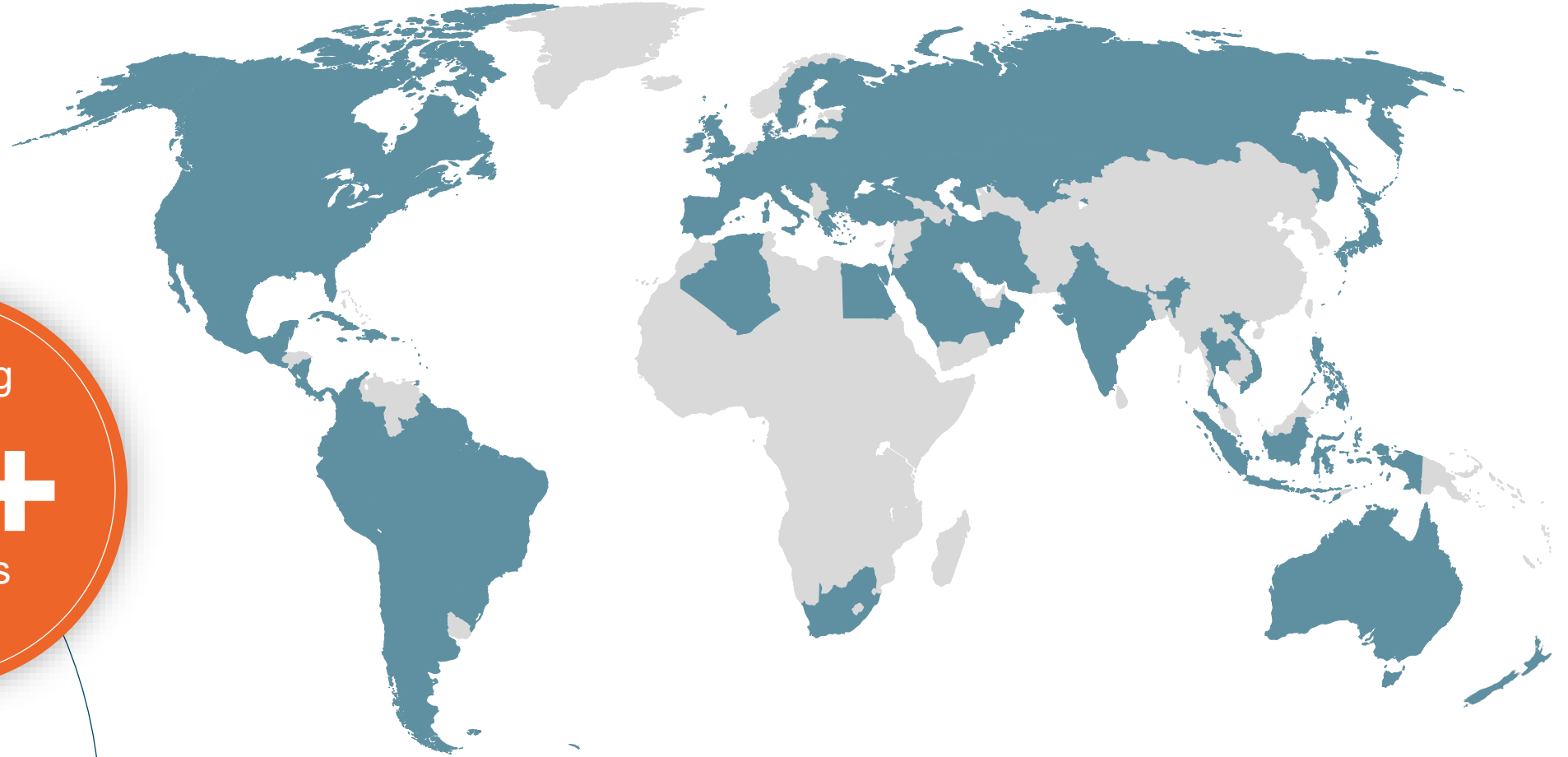
Broad **client base** ranging from blue-chip multi-nationals to start-ups



GLOBAL ELECTRODE SUPPLIER



Supplying
75+
Countries



THE ELECTRODE EXPERTS



» 20+ year design and manufacture of defibrillation and ECG electrode experience

» Experienced R&D engineers, production and quality team with in-depth understanding of the specific requirements for multiple electrode types

» Compliance specialists, building technical documentation to support your regulatory approval application

» Offering a full suite service from concept through design to manufacture

» Our experience means that our designs put usability at the forefront of our products



Hospital, EMS, Public and Aviation use



Longest Shelf-life in the market of 5.5yrs



Customisable shape and active area



Optimised form



Technical file generation and design change control



Fully compliant to material regulations

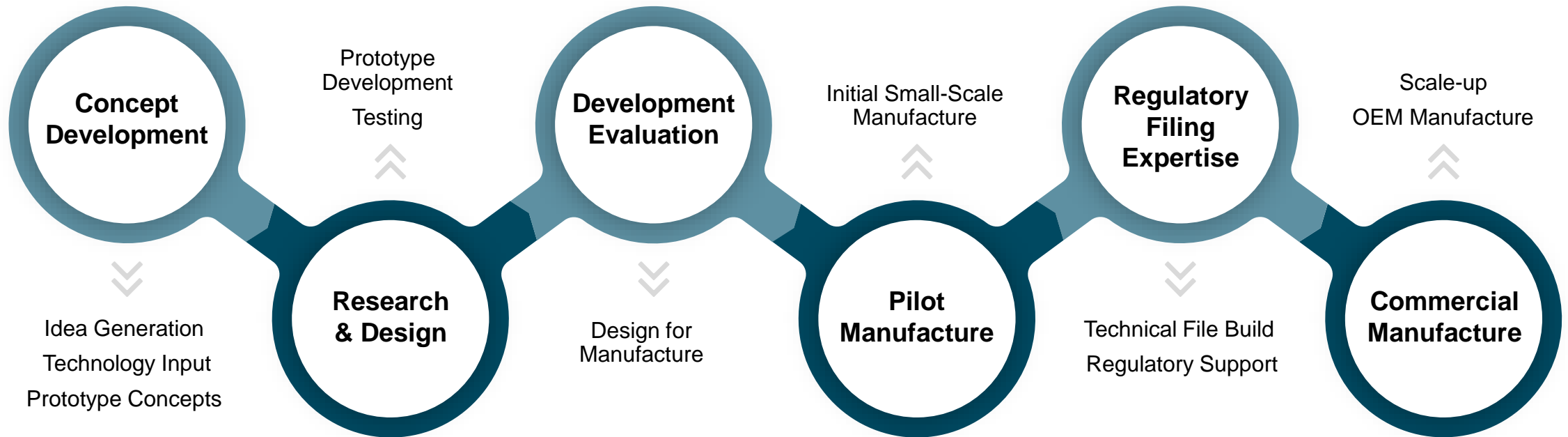


Assembly economies

Key company focus is on obtaining bio-signals from the body using material and sensor technologies as a gateway:

- Cardiac rhythm for ECG & Defib use
- Prediction of labour onset
- Hydration status derived from impedance measurements

END TO END PROCESS FROM CONCEPT TO COMMERCIAL MANUFACTURE



Complete offering that few can match

CONCEPT DEVELOPMENT, RESEARCH AND DESIGN



Design

- Screen printed electrodes
- Electrode design for ECG / defib electrodes
- Pouch design
- Outer packaging design including UDI/GTIN
- Project management defined process

Design Standards

- ISO: 60601
- Risk management ISO:14971
- Biocompatibility ISO:10993

Design Testing & Manufacturing Testing

- Validated manufacturing processes & equipment
- ECG Testing to AAMI: EC12
- High voltage defib testing ISO: 60601
- In process destructive testing
- Design change validations
- Process validations
- Retained samples & batch record management
- Certificate of conformance for product release
- Environmental chambers for temperature and humidity
- Test suite for ECG and defib electrodes

A team expert in researching, designing and engineering to deliver commercial success

MANUFACTURING CAPACITY AND CAPABILITY



Key Capabilities

- Screen printing electrode manufacturing
- Pouch design and manufacturing processes
- Range of specific manufacturing processes e.g., packaging of electrodes
- Customised assembly tooling including those on standard equipment
- Packaging and lamination
- Prototype & full-scale commercial manufacturing



Dedicated electrode manufacturing facility

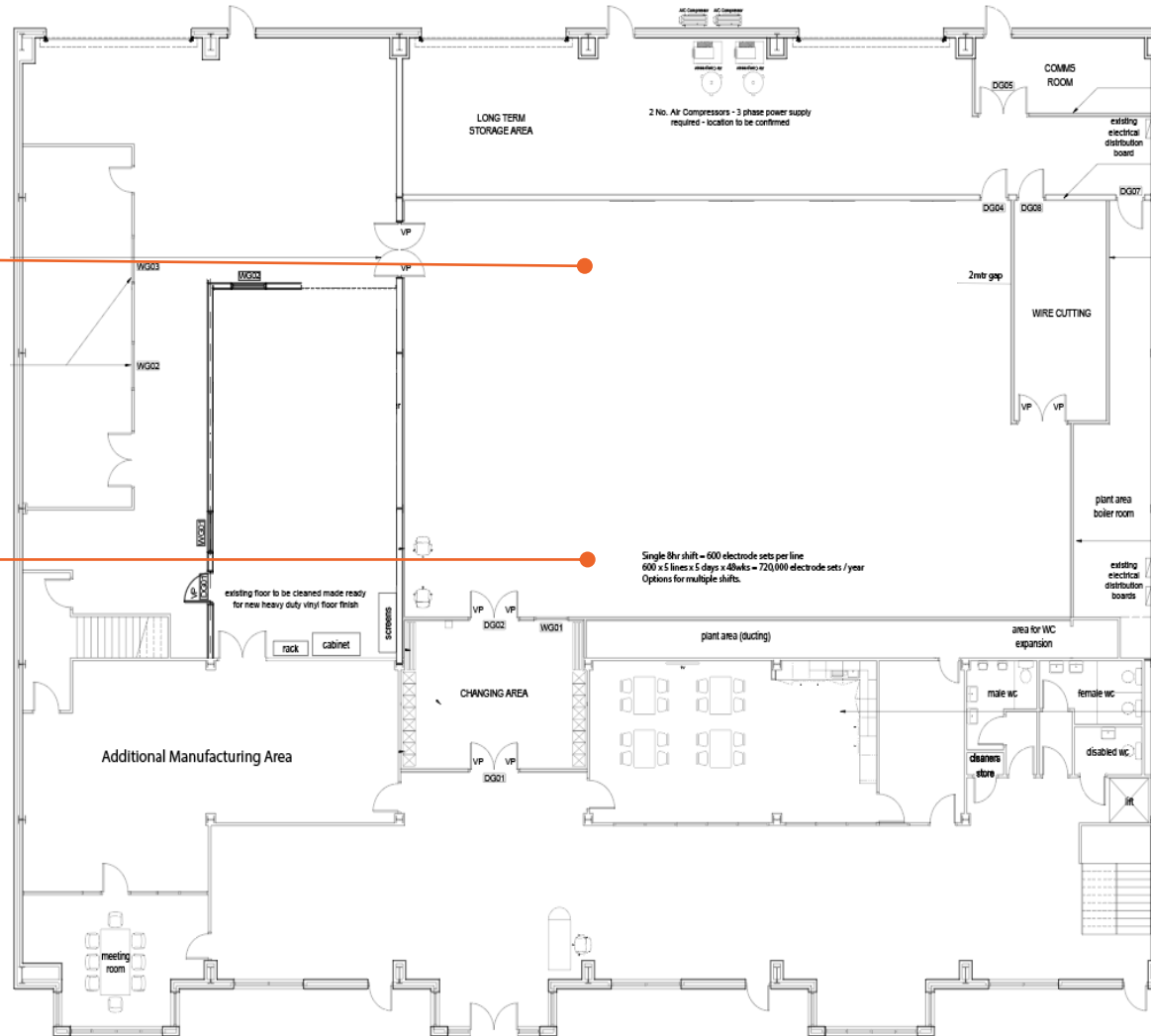


- Whatever your volume requirements, we have the capacity and capability to deliver
- Currently on Approved Vendor List (AVL) for number of blue-chip companies
- Available capacity for significant expansion of manufacturing and development projects
 - › Ability to reconfigure manufacture floor should capacity needs require
- Highly trained, multiskilled, flexible workforce

Cost effective and validated manufacturer

We pride ourselves in delivering excellent electrode design, validated and cost-effective manufacturing processes

MANUFACTURING SUITE



Our Proud Manufacturing Record

- Manufacturing commercially for over two decades
- Since 2010, over 1.5M+ electrodes manufactured and delivered to our clients
- 100% order fulfilment
- Regulatory authority audits consistently passed (FDA Inspections and ISO 13485 audits)
- Continual improvement and commitment to excellence

INTELESENS' DEFIB ELECTRODES



Longest Shelf-Life of 5.5 years



Lead wire cut to customer needs



Customisable shape and active area



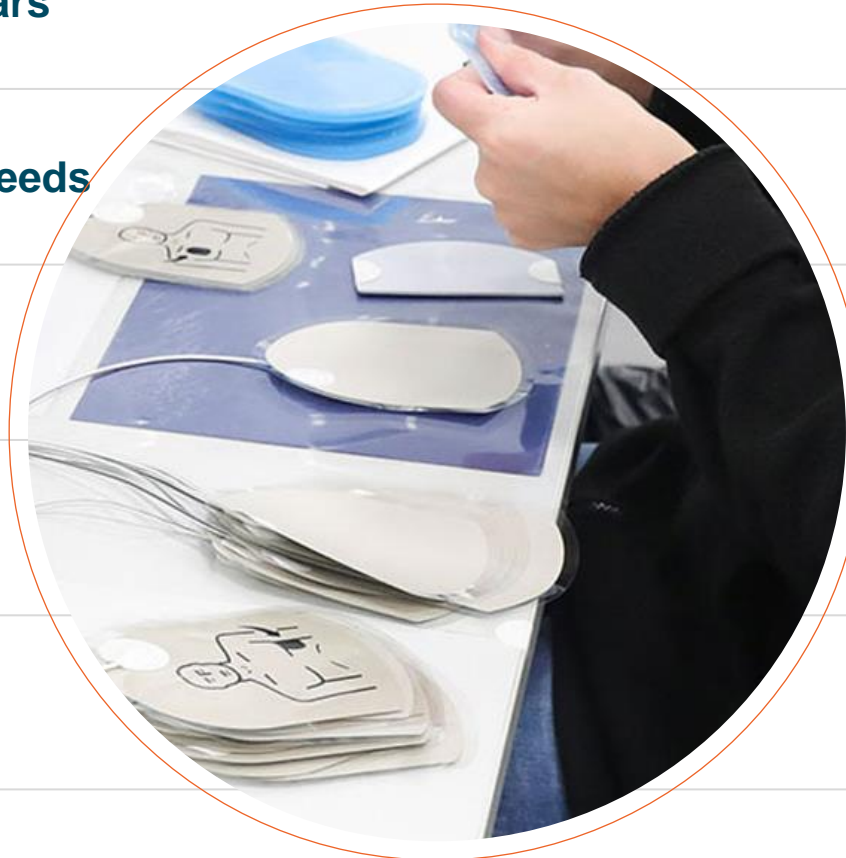
Optimised form



Biocompatible



Fully compliant to material regulations (Proposition 65, RoHS, REACH)



Simplified Design for manufacture



Adult and paediatric options



Hospital, EMS, Public and Aviation use



All packaging and labelling requirements customisable



Manufactured to highest regulatory standards



Technical file generation and design change control



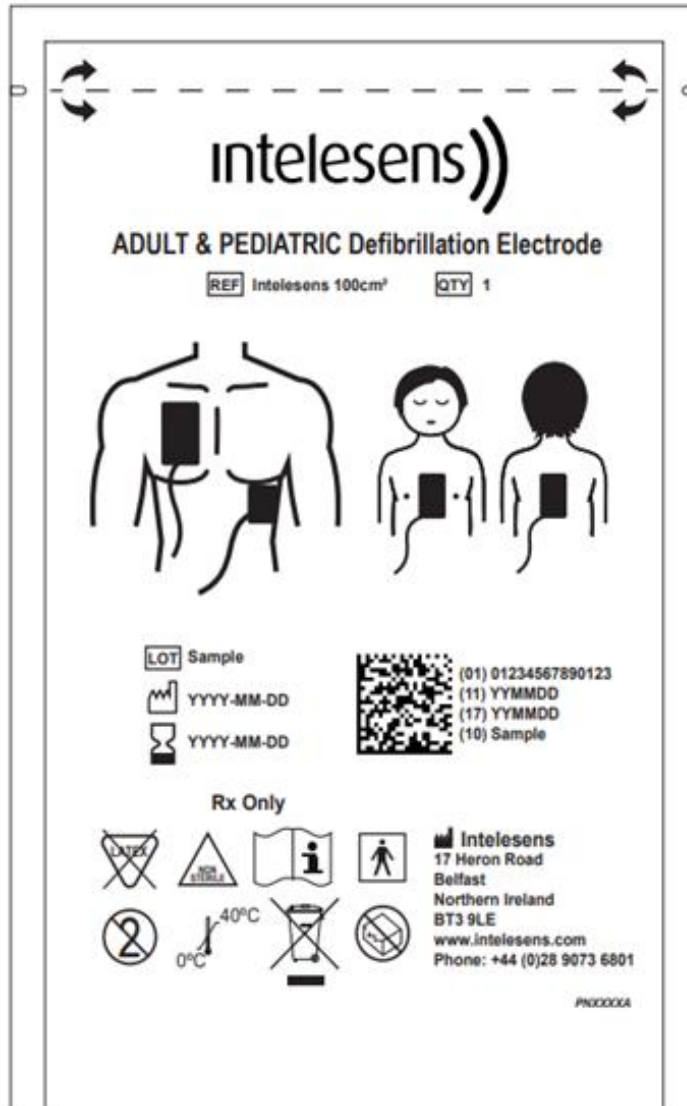


Defibrillation Performance

The Intelesens Defibrillation 100cm² Electrode Assembly:

- Shelf life of 5.5 yrs.
- Operates as specified between 0°C and 50°C
- Performs up to 50 defib shocks at 360J
- Provides 60 minute pacing capability
- Enables fast return from shock delivery to ECG monitoring
- Demonstrates low impedance for better energy delivery to the patient
- High voltage defib testing ISO 60601-2-4





Bespoke Defibrillator and ECG Electrode Solutions

- Design, development, validation & manufacturing excellence
- Designed and produced with the customer as legal manufacturer
- Technical File generation and design change control
- Intelesens certified to ISO 13485

Defibrillator Electrode Key Features

- Adult and pediatric population
- 5.5 year shelf life
- Customizable shape and active area
- Minimum of 1 meter leadwire
- Optimized form
- Screen printed conductor
- Preconnect system
- Radio translucent *
- Product designed to BS EN 60601-2-4
- Meets biocompatibility standards ISO 10993-5 & ISO 10993-10

For full range of Intelesens capabilities and further information contact: electrodes@intelesens.com or visit www.intelesens.com

* Radio Translucent testing underway



Materials

- Specific supplier contracts – MOQs etc – Second source where applicable
- Custom & 'off the shelf' materials & services
- Management of supply chain including contingency stocking and shelf life control



Equipment

- Tooling and artwork designs
- Stamping tools
- Screen printing artwork designs
- Calibration processes & equipment installation process
- Semi automatic assembly line



Design files

- Design change validations
- Process validations
- Retained samples & batch records

Providing a range of services to fit your exact needs



Quality Standards and Compliance



- › Complying to ISO 13485 Quality Management System
 - › BS EN 60601-2-4/ IEC 60601 for cardiac defibrillators & electrodes
 - › ISO 10993 for biocompatibility
 - › ISO 15223 for labelling
 - › ISO 14971 for risk management
 - › AAMI standards
- › Expertise in supporting
- › CE Marking
 - › FDA Regulatory submission (510K, PMA)

Regulatory Expertise



- › Technical file generation
- › Regulatory body submission support

Using our wealth of experience and expertise to supply to the market to the highest quality standards



THE COMPLETE ELECTRODE EXPERT & PARTNER

World leading electrode supplier

- We develop and manufacture electrodes for multiple companies worldwide (under exclusive supplier arrangements) including blue-chips
- We have been manufacturing and developing electrodes since 2000, to become one of the leading suppliers of customised electrodes in the market
- Intelesens facility includes R&D, Manufacturing, Logistics and Customer Service

Cost effective and validated manufacturer

- We pride ourselves in delivering excellent electrode design, validated and cost-effective manufacturing processes

Flexible solution to meet your needs

- Whatever your requirements, we have extensive experience supported by accredited in-house facilities to provide an end-to-end solution for your customised electrode solution

Supplying the market to the highest quality standards

- Complying to ISO 13485

Capacity to meet your market needs – now and into the future

- Whatever your volume requirements, we have the capacity and capability to deliver



THANK YOU