



Alert-it Care Alarms

Fernie House
Jackson Street
Coalville Business Park
Leicester LE67 6NR

Admin 01530239900
Email: lyndasy@alert-it.co.uk

Dated	October 2019
Our ref:	Clinical Evaluation

Invitation To Tender

Dear Sir/Madam,

A little about ourselves... iTs Designs Ltd T/a Alert-it Care Alarms is a privately SME based in Leicestershire specialising in assistive technology certified to BSI 13485-2016 to design and manufacture Class 1 medical device. Our technology was founded by David Godfrey over 26 years ago to help a local family whose daughter, Jessica, was suffering Tonic/Clonic epileptic seizures at night. This then led onto further innovations being created, leading to offering technology to support a range of epilepsy seizure types, falls prevention and dementia care. Our customer profile ranges from parents, small and large care homes and Hospitals. Our products are also available from distributors throughout Europe.

Alert-it is one of the UK's leading innovators and forward-thinking manufacturers specialising in the design, production, distribution and support of care alarm systems. Our technology has grown to incorporate many innovations such as failsafe radio technology to ensure the information is being received and notify of any issues such as lost signal, low battery etc. Our aim with our products is to try and reduce the stress of care.

We pride ourselves on producing class one medical devices to BSI13485-2016. To allow us to continue with, and introduce new products under the new Medical Devices Regulations including supporting the NHS five-year priorities from 2020, we require the following, as stated by the MHRA:

Clinical data' - information concerning safety or performance that is generated from the use of a device and is sourced from the following:

— ***Clinical Investigation(s)*** of the device concerned, *clinical investigation plan'* means a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organisation and conduct of a clinical investigation.

Our new project is to collaborate with a team who can test our products in a ***Clinically Controlled*** environment and record the results in an official way. We are fully open to ideas and offers as to how this could take place. This could be undertaken in a range of ways from bench testing or simulations to human trials. Once the items have been tested, we require this formally writing up as a Clinical Evaluation.

The Approach Solution

Products requiring clinical evaluation will be supplied to the successful party. A representative from Alert-iT will be available throughout process to support and provide an understanding of each product. Marketing specifications, product literature and handbooks will be provided for each product. All documentation will be managed through our quality management process.

Pricing

Please provide a quotation with breakdown of prices for the project testing, writing up of the results and the review of the results written as a Clinical Evaluation.

Should you require any further assistance, please feel free to contact me on 01530 239900. All applications should be emailed to lyndasy@alert-it.co.uk The closing date for the application is 28th October 2019

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Tony Bullars', with a stylized, cursive flourish.

Tony Bullars
Director