

4 March 2020

**Intelligent Ultrasound Group plc**  
("Intelligent Ultrasound" or the "Group")

**ISO13485 certification for medical devices**

Intelligent Ultrasound Group plc (AIM: MED) the ultrasound artificial intelligence (AI) software and simulation company, announces it has formally received ISO13485:2016 certification for its Quality Management System following review by the certification body LRQA. ISO13485:2016 is the internationally recognised quality standard to ensure the consistent design, development, production, installation and sale of medical devices that are safe for their intended purposes.

The Group's Clinical AI division is in the process of bringing a range of AI-based image analysis software products to market and obtaining ISO13485:2016 certification is required to bring the Group's real-time AI image guidance software products through regulatory approval.

**Stuart Gall, Group CEO, commented:** *"With our first major AI licensing agreement signed last year and commercial discussions progressing for our second AI software product, this is an important milestone for the Group as we look to bring the first Intelligent Ultrasound AI products to market in 2020."*

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## About Intelligent Ultrasound Group

Intelligent Ultrasound (AIM: MED) develops artificial intelligence-based clinical image analysis software tools for the diagnostic medical ultrasound market and hi-fidelity virtual reality simulators for the ultrasound training market.

Based in Cardiff and Oxford in the UK, Atlanta in the US and with representation in Beijing in Asia, the Group operates two divisions:

### *Clinical AI Division*

Focuses on developing deep learning-based algorithms to make ultrasound machines smarter and more accessible. Products in development include ScanNav which uses machine-learning based algorithms to automatically identify and grade ultrasound images to provide scan assessment and audit of protocol-based ultrasound scanning in fetal medicine; and AnatomyGuide, which aims to simplify ultrasound-guided needling by providing the user with real-time AI-based needle guidance software for a range of medical procedures.

### *Simulation Division*

Focuses on hi-fidelity ultrasound education and training through simulation. Its three main products are the ScanTrainer OBGYN training simulator, the HeartWorks echocardiography training simulator and the BodyWorks Eye Point of Care and Emergency Medicine training simulator. To date over 850 simulators have been sold to over 500 medical institutions around the world.

[www.intelligentultrasoundgroup.com](http://www.intelligentultrasoundgroup.com)

