contextflow Earns Coveted MDR Certificate for Medical Devices

Fresh off its Series A funding, the Austrian-based AI in radiology startup contextflow has announced it has received its MDR certificate for medical devices.

VIENNA, AUSTRIA, June 23, 2021 /EINPresswire.com/ -- contextflow, a leading provider of artificial intelligence for medical image analysis, announced it has received its Medical Device Regulation (MDR) certificate on June 7th, making it only one of 11 AI solutions to have secured this certification. Moreover, it is only one of 4 MDR-certified manufacturers to offer a solution for chest imaging at the moment.

contextflow's Regulatory & Quality Assurance Team Members (l to r): Markus Krenn (Chief Product Officer), Magdalena Kedwani (Head of Regulatory Affairs), Nilaykumar Patel (Head of Quality Management); Copyright: contextflow

On May 26th, 2021, the new "Regulation (EU) 2017/745" came into force replacing the older "Medical Device Directive 93/42/EEC". The new regulation is designed to make the EU legislative framework more robust while keeping in mind better protection of public health and patient safety. Not only is this new regulation aimed at facilitating patients' access to devices in the European market in a very highly organised manner, but it also provides manufacturers comparatively detailed information on fulfilling the requirements, especially when it comes to safety and efficacy of medical devices.

"Having an MDR certificate signifies that the contextflow complies with the applicable regulatory requirements defined in the EU regulation 2017/745 on medical devices and allows the company to develop and market class IIa medical device software for radiology in the EU," explains Nilaykumar Patel, Head of Quality Management.
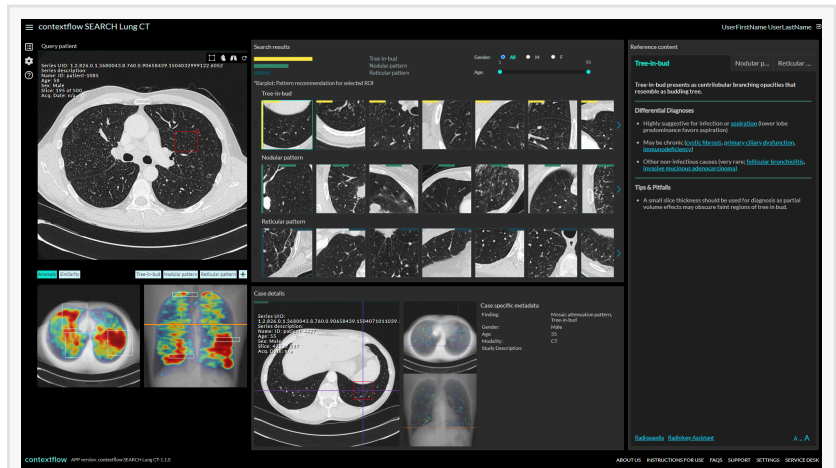
Only 20 notified bodies in the entire EU are allowed to certify medical device manufacturers,

which has resulted in long waiting periods for manufacturer audits, particularly during the pandemic. contextflow began its certification process back in 2018.

Magdalena Kedwani, Head of Regulatory Affairs at contextflow continues, "This certification is key to EU market entry, and we're very fortunate to be one of the first to have received it. We definitely could not have done this on our own and want to thank our consultant Martin Schmid from encotec who has supported us since 2019 in building a solid Quality Management System and preparing us for the MDR audit."

contextflow SEARCH Lung CT identifies 19 different patterns in Lung CTs, including those related to COVID-19.

contextflow's core technology is [SEARCH Lung CT, a 3D image-based search engine](#) that detects disease patterns in 3D medical images like CTs and MRs. It is currently being utilized by radiologists on lung CTs, identifying 19 different patterns (including those related to COVID-19), making it the only clinical decision support system of its kind. With this certificate, SEARCH Lung CT is now officially ready to be sold in the EU, helping radiologists solve challenging cases.

"

Having an MDR certificate allows the company to develop and market class IIa medical device software for radiology in the EU."

contextflow Head of Quality Management Nilaykumar Patel

About contextflow:
contextflow is a spin-off of the Medical University of Vienna (MUW), supported by the Technical University of Vienna (TU) and European research project KHRESMOI. Founded by a team of AI and engineering experts in July 2016, the company received the BCS Search Industry Most Promising Startup Award 2016, the 2017 Digital Innovation Award by the Austrian Ministry of Education, Science & Research, and was selected as one of 19 startups out of 700+ applications for the 2018 Philips HealthWorks accelerator. The Central European Startup Awards awarded us Best Healthcare Startup 2019 - Austria, and Forbes DACH listed us as one of the top AI30 startups for 2020.

Julie Sufana
contextflow GmbH
jsufana@contextflow.com
Visit us on social media:
[Twitter](#)

This press release can be viewed online at: https://www.einpresswire.com/article/544548658