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IRRAS provides update on CE mark Re-Certification of IRRAflow

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US, other global markets, and worldwide regulatory submissions shall remain the main focus for the rest of the year



IRRAS AB (IRRAS), a commercial-stage medical technology company focused on developing and commercializing innovative solutions for neurocritical care, announced that it received a response from G-MED, its designated European Notified Body, that requests clarifications and additional information regarding the company's CE Mark re-certification of IRRA*flow* Catheter.

G-MED has asked for additional technical clarifications and updates of certain previous older reports performed by the previous Swedish development partner. The requests are part of the routine review cycle and will be addressed by IRRAS in a timely manner.

"We finally received the feedback from G-MED after a lengthy period," said Kleanthis G. Xanthopoulos, Ph.D, President and CEO of IRRAS. "We believe that all of their comments are addressable. Having established a productive dialogue with the notified body, we now have a clear path forward, and we anticipate responding shortly to the list of questions. We will continue to work closely with the G-MED team to reintroduce this innovative medical device to the EU market, offering patients, neurosurgeons, and hospitals an effective, intelligent solution to treat intracranial bleeding. In the meantime, the launch of IRRA*flow* in the United States is on track since our 510(k) clearance last year, and our plans to open other global markets remain unchanged."