IRRAS announces receipt of updated ISO 13485:2016 certificate and updated CE marks valid until 2021 for two of three IRRA*flow*™ products - remaining CE mark expected in the near future

Stockholm, Sweden May 9, 2018 – IRRAS AB (NASDAQ Stockholm: IRRAS), a commercial-stage medical technology company focused on designing, developing and commercializing innovative solutions for brain surgery, today announced that it received an updated ISO 13485:2016 certificate and updated CE marks for its control unit and tube set. Both products are class II products. The ISO certificate and CE marks are valid until 2021. It is typical for a class III product, such as the IRRAS catheter, to require more time for auditing. Regardless, an updated CE mark for the IRRAS catheter is expected in the near future.

IRRAS has completed an audit of its quality system and IRRA*flow* products with the company's new Notified Body, LNE/G-MED. A Notified Body is an entity that has been accredited by a Member State in the EU to assess whether a product to be placed on the market meets certain preordained standards. IRRAS previous Notified Body Intertek (AMTAC) decided earlier not to continue to support certain device categories. Intertek's customers within these categories therefore had to get new ISO and CE certificates from a new Notified Body. This has created a long list of companies that are seeking to be re-certified.

Following completion of the audit by LNE/G-MED, IRRAS was issued new CE certificates for two of its three products while the third CE mark for the catheter is under review and is expected soon. As the catheter is a class III product the recertification takes a somewhat longer time.

"We are happy to have both rapidly identified a new Notifying Body and to have received an updated ISO and CE mark for two of our products. We are confident that we will have the remaining CE mark for the catheter in place shortly. Potentially the delay can affect sales in Q2 but we do not foresee any effect on sales for the full year", said Kleanthis G. Xanthopoulos, Ph.D., President and CEO of IRRAS.

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About IRRAS

IRRAS AB (NASDAQ Stockholm: IRRAS) is a publicly-traded, commercial-stage medical technology company focused on designing, developing and commercializing innovative solutions for brain surgery. The Company's initial product, IRRA*flow*™, addresses the complications associated with the current treatment methods of intracranial bleeding with a dual lumen catheter that combines active irrigation with ongoing fluid drainage. Regularly during treatment, the catheter is automatically flushed to prevent common catheter occlusions from forming. Additionally, because IRRA*flow* is a completely closed system, it may also potentially reduce the documented infection risk of these procedures.

With its unique product portfolio, protected by property patents and patent applications, IRRAS is well-positioned to establish a leadership position in the medical device market. IRRAS maintains its headquarters in Stockholm, Sweden, with corporate offices in Munich, Germany, and San Diego, USA. For more information, please visit www.irras.com.