IRRAS Provides Update on the Recertification Process of the CE Mark for the IRRA*flow*® Catheter

- *Due to large backlog of applications, the Notified Body, LNE/G-MED, now expects completion of the process around year's end*

Stockholm, Sweden, October 4, 2018 – IRRAS AB (Nasdaq First North Premier: IRRAS) announced today that it has received further information from its Notified Body, LNE/G-MED, regarding the CE Mark of the IRRA*flow* catheter. The Notified Body completed its initial review of the IRRAS recertification application and has provided a list of questions and requests for some clarifications. These requests by LNE/G-MED should all be addressable in existing IRRAS documentation, and the company plans to submit its response within a couple of days. However, due to the large backlog of applications, LNE/G-MED now estimates completion of the process around year's end.

"The feedback from the Notified Body is addressable, and we will respond shortly as we have all the documents requested," said Kleanthis G. Xanthopoulos, Ph.D., President and CEO of IRRAS. "However, the delay is frustrating to us, our clinicians, and, importantly, the patients. While the delay has affected our European sales for this year, our long-term sales projections have not been changed. If anything, the future outlook of IRRAS has improved with the recent FDA approval of IRRA*flow* in the US." he continued.

For more information, please contact:
Fredrik Alpsten
CFO and Deputy CEO
+46 706 67 31 06
fredrik.alpsten@irras.com

About IRRAS

IRRAS AB (Nasdaq First North Premier: IRRAS) is a publicly-traded, commercial-stage medical technology company focused on developing and commercializing innovative solutions for brain surgery. The Company's initial product, IRRA*flow*®, addresses the complications associated with the current methods of managing intracranial fluid by using a dual lumen catheter that combines active irrigation with ongoing fluid drainage. IRRA*flow* received FDA clearance in July 2018.

Regularly during treatment, the IRRA*flow* catheter is automatically flushed to prevent common catheter occlusions from forming. Because IRRA*flow* is a completely closed system,

it is designed to reduce the documented infection risk of these procedures. Additionally, IRRA*flow* incorporates ICP monitoring and uses a proprietary software to regulate treatment based on desired pressure levels.

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, California, USA. For more information, please visit www.irras.com.

IRRAS AB (publ) is listed on Nasdaq First North Premier. Wildeco is certified adviser of the company.