**Stockholm, 13 December 2017**

# IRRAS announces voluntary recall on its IRRA*flow*™ device due to an isolated incident of a battery manufacturing failure

IRRAS AB (IRRAS), a commercial-stage medical technology company focused on designing, developing and commercializing innovative solutions for various brain pathologies, announces that it has notified customers of a voluntary recall and a temporary stop of selling of IRRA*flow*™, the company's closed-circuit medical device for the treatment of intracranial bleedings. The reason for the voluntary recall is that the battery, supplied by a well validated external manufacturer, overheated on an IRRA*flow*™ control unit while charging in standby mode during a routine office demonstration. No patients were present and no procedures were scheduled, as this was only an office demonstration. IRRAS is taking this action as a precaution. IRRAS is now working with the battery supplier to understand the specific cause for the failure of the battery. As part of our quality systems all batteries undergo charge and discharge testing as well as a 24-hour use period to screen for any potential manufacturing defects. Therefore, IRRAS believes this is an isolated incident of a manufacturing failure. Relevant regulatory bodies will be notified of the voluntary recall.

As a reminder of the impact IRRA*flow*™ has on neurosurgery critical care of intracranial bleedings, to date, IRRA*flow*™ has been used in 94 clinical procedures in four different EU countries. There have been no occlusions or blockages in the catheters and no infections reported. Of the 94 real-world clinical cases, the total treatment time in the hospital for each patient was significantly reduced from the current standard of care treatment. IRRAS does not anticipate any long-term impact in the adoption and clinical use of its IRRA*flow*™ device due to this isolated incident, especially given the successful clinical usage thus far, and expects sales to resume as soon as the new batteries are available.

The voluntary recall will affect the 2017 sales of IRRA*flow*™ on two fronts, both as the sales have now temporary stopped and IRRAS has offered to repurchase the previously sold products. The company has already initiated a process to replace the specific lot of batteries in the control units. IRRAS estimates that the replacement and validation of the new lot can be ready within 1 to 3 months, therefore delaying the sales plan accordingly. The 2020 objective of sales exceeding 250 MSEK remains intact.

## About IRRAS

IRRAS is a commercial-stage medical technology company focused on designing, developing and commercializing innovative solutions for various brain pathologies, with a goal of dramatically improving patient outcomes, reducing patient-time in the intensive care unit and medical ward, and providing significant health economic benefits to hospitals and healthcare providers. The Company's initial product focus is on intracranial fluid management solutions that utilize its proprietary platform technology, IRRA*flow*™, which is a CE-marked, fully integrated, closed-circuit medical device system that enables intelligent intracranial fluid management as well as accurate, real-time monitoring of intracranial pressure.

With its unique product portfolio, protected by key intellectual property patents and patent applications, IRRAS is well-positioned to improve patient outcomes and establish a leadership position in the medical device market. IRRAS maintains its headquarters in Sweden with corporate offices in Germany and La Jolla, CA, USA. For more information, please visit www.irras.com.

**Investor and Media Contact:**

Fredrik Alpsten
CFO and Deputy CEO
+46 706 67 31 06
fredrik@irras.com

This information is information that IRRAS is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact person above, on 13 December 2017 at 07.25 a.m. (CET).