IRRAS receives extension of its MDSAP certification and scope expansion of MDSAP & ISO 13485:2016 certifications

- *After completion of successful verification audit by its notified body DEKRA, IRRAS' Medical Device Single Audit Program (MDSAP) certification has been extended for three years until July 2024*
- *The company's MDSAP/ISO 13485:2016 certification will also have a scope upgrade to include company's new manufacturing facility following the audit's site inspection*
- *The expanded ISO certification now allows product manufactured in IRRAS' new facility to be shipped globally*

Stockholm, July 21, 2021 – IRRAS AB, a commercial-stage medical technology company with a comprehensive portfolio of innovative products for neurocritical care, announced today that it has successfully completed an in-person verification audit of its Quality Management System (QMS) by DEKRA, the company's notified body. Earlier this year, IRRAS announced that the company had received certification of its QMS under the Medical Device Single Audit Program (MDSAP). As a result of this verification audit, the company's MDSAP certification that covers both its IRRA*flow* and Hummingbird ICP Monitoring product lines will now be extended for two additional years and will remain valid until July 2024.

This DEKRA audit also included a thorough inspection and validation of IRRAS' new manufacturing facility, IRRAS South, Inc. After this successful audit, IRRAS' corporate ISO 13485:2016 certification will be expanded to also cover this facility, which has now been audited with no major findings by both the United States Food and Drug Administration (FDA) and DEKRA, IRRAS' European regulatory representative. IRRAS can now manufacture and globally ship medical devices from this facility based on these positive audit outcomes.

MDSAP is a stringent audit process that was established to enable medical device manufacturers to undergo one single audit of their QMS that covers the requirements of participating regulatory jurisdictions in Australia (TGA), Brazil (ANVISA), **Canada** (Health Canada), **Japan**(MHLW) and the **United States** (FDA). This extended MDSAP certification will support IRRAS' efforts to secure product regulatory clearance in these new markets.

"This recently completed audit is another strong confirmation of the meaningful progress made by our IRRAS team," said Will Martin, President and CEO of IRRAS. "Not only does the extension of our MDSAP certificate allow us to pursue meaningful regulatory approvals over the next three years, but it is an important milestone to receive ISO certification for IRRAS' first in-house manufacturing facility. This accomplishment validates our team's collective commitment to quality and also secures necessary supply of IRRA*flow* capital equipment for our growing number of customers around the globe."

About IRRAS
IRRAS is a global medical care company focused on delivering innovative medical solutions to improve the lives of critically ill patients. IRRAS designs, develops, and commercializes neurocritical care products that transform patient outcomes and decrease the overall cost of care by addressing complications associated with current treatment methodologies. IRRAS markets and sells its comprehensive, innovative IRRA*flow* and Hummingbird ICP Monitoring product lines to hospitals worldwide through its direct sales organization in the United States

and select European countries as well as an international network of distribution partners.

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 is listed on Nasdaq Stockholm (ticker: IRRAS).

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The information was released for public disclosure, through the agency of the contact person above, on July 21, 2021 at 08:30 (CET).