**ASX Announcement**

# UPDATE ON CE MARK CERTIFICATION

**26 September 2019 – Minneapolis, United States – Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (ASX:**IMR**) today provides the following update on the CE mark certification process for the Vision-MR Ablation Catheter.

Imricor advises that the CE mark certification process for the Vision-MR Ablation Catheter is progressing, and no issues or concerns about the safety and performance of the catheter have been identified by the Company's Notified Body, TÜV SÜD. The Company is engaging regularly with TÜV SÜD, and while they have been responsive and engaged, the Company understands that TÜV SÜD is nonetheless experiencing a substantially increased workload and associated resources strain, due to a material reduction in the number of Notified Bodies as well as the upcoming adoption of the new EU Medical Device Regulation.

Due to this increased burden on TÜV SÜD, Imricor no longer expects that the certification process will conclude by the end of Q3 2019, as was previously anticipated and disclosed in the Company's prospectus.

Whilst Imricor continues to believe that the review process will be finalised shortly, the exact date of CE mark certification is not certain, and therefore it is not possible at this time for the Company to determine the impact, if any, on the financial forecasts disclosed in the prospectus for FY19. However, if CE mark is received in early October, Imricor does not believe the delay will have a material impact on the financial forecasts for FY19. If CE mark comes later in October, there is likely to be an impact on the financial forecast, which the Company will assess once it has further clarity on timing.

Separately, lab adoption is progressing well despite the prolonged certification process and the Company continues to identify additional hospitals interested in early adoption of MR-guided atrial flutter ablations.

Commenting on the current status of the process, Imricor Chairman and CEO, Mr Steve Wedan, said "While we are disappointed with this delay, we are encouraged by our engagement with TÜV SÜD and that the certification process is moving forward at a steady pace. We are eagerly looking forward to launching our MR-guided ablation solution in the EU as soon as possible."

ENDS

**Further Information**

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## About Imricor

Imricor Medical Systems, Inc. (ASX:IMR) is a leading developer of innovative MRI-compatible medical devices which can be used to carry out MRI-guided cardiac catheter ablation procedures. Headquartered in the US, Imricor seeks to make a meaningful impact on patients, healthcare professionals, and healthcare facilities around the world by increasing the success rates and bringing down the overall costs of cardiac catheter ablation procedures.

## Foreign Ownership Restrictions

Imricor's CHESS Depositary Interests (**CDIs**) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (**Securities Act**) for offers which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. As a result of relying on the Regulation S exemption, the CDIs are 'restricted securities' under Rule 144 of the Securities Act. This means that you are unable to sell the CDIs into the US or to a US person for the foreseeable future except in very limited circumstances after the expiration of a restricted period, unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a 'FOR US' designation on the Australian Securities Exchange (**ASX**). This designation restricts any CDIs from being sold on ASX to US persons. However, you are still able to freely transfer your CDIs on ASX to any person other than a US person. In addition, hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

## Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on the Company's management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These include, without limitation, EU commercial market acceptance and EU. sales of our product as well as our expectations with respect to our ability to develop and commercialise new products. Management believes that these forward-looking statements are reasonable when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Imricor does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Imricor may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.