

HepaFat-Scan[®] listing on the ARTG and CE Mark

Resonance Health Limited (ASX; RHT) has received approval from the Therapeutic Goods Administration (TGA), to list its HepaFat-Scan[®] product on the Australian Register of Therapeutic Goods (ARTG).

HepaFat-Scan[®] is a software medical device that enables the non-invasive measurement of fatty liver using magnetic resonance imaging (MRI).

This listing on the ARTG is an important milestone for the Company as it prepares to launch the product in Australia and internationally. The listing on the ARTG enables Resonance Health to supply HepaFat-Scan[®] in Australia and to apply the CE mark, enabling the product to be sold in Europe.

Resonance Health gained clearance to market HepaFat-Scan[®] in the United States by the US Food and Drug Administration (FDA) in December 2013.

The primary risk factors for fatty liver disease are obesity and metabolic syndrome. Fatty liver disease is considered the most common liver disease in the western world affecting 20-30% of the population, rising to 50-90% of the obese population and approximately 50% of the diabetic population.

Fatty liver disease can be asymptomatic and is often undiagnosed. Currently, the gold standard for diagnosis is a liver biopsy with a visual estimate of fat by a pathologist. HepaFat-Scan[®] provides a non-invasive solution to researchers and clinicians that need to measure the liver fat content of their patients.

HepaFat-Scan[®] reports the percentage of the liver that is fat. It is the first and currently the only FDA approved method for the quantitative measurement of liver fat that has been validated against independent measurements of fat in liver biopsy specimens in a clinical study. HepaFat-Scan[®] is easy to implement and uses standard MRI scanners available in most hospitals and radiology facilities. Combined with Resonance Health's core lab services, HepaFat-Scan[®] is an ideal tool for clinical trials of new treatments for non-alcoholic fatty liver disease (NAFLD).

By Order of the Board, Resonance Health Limited

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