CARMAT receives MDR CE marking for its Aeson® artificial heart

Paris, July 28, 2025 – 6:00 pm CEST

CARMAT (FR0010907956, ALCAR), designer and developer of the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from advanced biventricular heart failure (the "**Company**" or "**CARMAT**"), today announces that it has obtained CE marking under Regulation (EU) 2017/745 on medical devices (Medical Devices Regulation – MDR), which replaces the former Medical Device Directive (MDD 93/42/EEC). This new certification covers the bridge to transplant (BTT) indication and applies to the Aeson® system as a Class III active implantable medical device.

MDR CE marking certifies Aeson®'s compliance with the most stringent European regulatory requirements

The MDR CE marking certifies Aeson®'s compliance with the latest European standards and requirements relating to patient safety, clinical performance, risk management, and post-market surveillance. It was granted following a rigorous and comprehensive review conducted by the notified body DEKRA.

In December 2020, Aeson® had obtained CE marking in the bridge to transplant indication, under the Medical Device Directive (MDD), which was in force at the time. Since then, the MDD has been replaced by the Medical Device Regulation (MDR), which significantly strengthens the requirements to be met. Class III medical devices such as Aeson®, which were CE marked under the MDD before May 2021, have until May 2027 to obtain MDR CE marking. Failing to do so would mean the device could no longer be marketed in the European Union after this date.

The MDR certification confirms and reinforces Aeson®'s recognition by health authorities.

A strengthened regulatory foundation to support European and international growth and future extension of Aeson®'s indications

Obtaining MDR CE marking, well ahead of the transition deadline, means that from a regulatory perspective, Aeson® can continue to be marketed in the European Union[1] beyond May 2027.

This certification also reinforces the Company's position in view of a future expansion of Aeson®'s indications, notably towards destination therapy[2] (DT), as well as in its U.S. market access strategy, currently targeted for 2028.

As a reminder, Aeson® is currently the only CE-marked implantable total artificial heart.

Readers are also reminded that the Company is currently placed in receivership procedure (opened on July 1, 2025) and is therefore facing a very high risk of default, including in the very short term.

[1] and in other countries which recognize CE marking.
[2] Destination therapy (or DT): in this indication, Aeson® would be implanted permanently without subsequent heart transplantation.

Stéphane Piat, Chief Executive Officer of CARMAT, *concludes*: *"I would like to congratulate our teams on obtaining MDR CE marking for the Aeson® artificial heart, following an extremely demanding process that mobilized many of our employees for months. I would like to underline that Aeson® is, and currently remains, the only implantable artificial heart being CE-marked and thus marketed in Europe. In the particular context in which CARMAT currently finds itself, this MDR certification is a further independent recognition of Aeson®'s quality and performance by health authorities. From a regulatory perspective, we have thus already secured the right to continue marketing Aeson® across Europe even beyond 2027, for patients suffering from advanced heart failure. I hope we will successfully get out of the receivership procedure we are currently in, so that patients can effectively continue benefitting from our therapy going forward. Finally, I would like to add that the "MDR" CE marking is also extremely important in view of getting access to the U.S. market, and future extension of Aeson®'s indications towards permanent patient support."*

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About CARMAT

CARMAT is a French MedTech that designs, manufactures and markets the Aeson® artificial heart. The Company's ambition is to make Aeson® the first alternative to a heart transplant, and thus provide a therapeutic solution to people suffering from end-stage biventricular heart failure, who are facing a well-known shortfall in available human grafts. The world's first physiological artificial heart that is highly hemocompatible, pulsatile and self-regulated, Aeson® could save, every year, the lives of thousands of patients waiting for a heart transplant. The device offers patients quality of life and mobility thanks to its ergonomic and portable external power supply system that is continuously connected to the implanted prosthesis. Aeson® is commercially available as a bridge to transplant in the European Union and other countries that recognize CE marking. Aeson® is also currently being assessed within the framework of an Early Feasibility Study (EFS) in the United States. Founded in 2008, CARMAT is based in the Paris region, with its head offices located in Vélizy-Villacoublay and its production site in Bois-d'Arcy. The Company can rely on the talent and expertise of a multidisciplinary team of circa 200 highly specialized people. CARMAT is listed on the Euronext Growth market in Paris (Ticker: ALCAR / ISIN code: FR0010907956).

For more information, please go to www.carmatsa.com and follow us on LinkedIn.

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Name: **CARMAT**
ISIN code: **FR0010907956**
Ticker: **ALCAR**

Disclaimer

This press release may contain forward-looking statements regarding the Company's objectives and outlook. These forward-looking statements are based on the current estimates and anticipations of the Company's management and are subject to risk factors and uncertainties, including those described in its Universal Registration Document filed with the French Financial Markets Authority (Autorité des marchés financiers) (the "AMF") under number D.25-0345 (the "**2024 Universal Registration Document**"), available free of charge on the websites of CARMAT (www.carmatsa.com/en/) and the AMF (www.amf-france.org).

Readers' attention is particularly drawn to the fact that the Company is currently placed in receivership (opened on July 1, 2025) and is facing a very high risk of default, including in the very short term. The Company is also exposed to other risks and uncertainties, such as its ability to implement its strategy, the pace of development of its production and sales, the progress and results of ongoing or planned clinical trials, technological developments, the competitive landscape, regulatory changes, industrial risks, and all risks related to the management of the Company's growth. Forward-looking statements mentioned in this press release may not be achieved due to these factors or other unknown risks and uncertainties, or risks that the Company does not currently consider to be material or specific.

Aeson® is an active implantable medical device commercially available in the European Union and other countries recognising the CE mark. The Aeson® total artificial heart is intended to replace the ventricles of the native heart and is indicated as a bridge to transplant in patients with end-stage biventricular heart failure (Intermacs classes 1-4) who cannot benefit from maximal medical therapy or a left ventricular assist device (LVAD) and who are likely to benefit from a heart transplant within 180 days of implantation. The decision to implant and the surgical procedure must be carried out by healthcare professionals trained by the manufacturer. The documentation (clinician's manual, patient's manual and alarm booklet) must be read carefully to learn about the characteristics of Aeson® and the information required for patient selection and proper use (contraindications, precautions, side effects) of Aeson®. In the United States, Aeson® is currently only available as part of a feasibility clinical trial approved by the Food & Drug Administration (FDA).