

## MeMed Receives CE Mark for Two Pioneering Technologies: The MeMed BV™ Test and MeMed Key™ Point-of-Need Platform

*Cutting-edge instrument platform and a novel host-immune response signature test rapidly distinguish between viral and bacterial infections to improve patient outcomes*

HAIFA, Israel, June 2, 2020 – [MeMed Ltd.](#), a leader in host response-based solutions, today announced that it has received a CE Mark in Europe for use of its diagnostic test [MeMed BV™](#) and point-of-need platform [MeMed Key™](#).

“At its core, MeMed is about decoding the signals of the host-immune response to help physicians make better informed decisions that improve patients’ lives,” **said Eran Eden, MeMed’s co-founder and CEO.** “The CE-IVD mark brings us closer to impacting patients around the globe. We believe MeMed BV™ and MeMed Key™ will be a major addition to the clinical arsenal, improving outcomes for patients with acute infections, lowering healthcare costs and combating antibiotic resistance. We are indebted to the United States Department of Defense and the European Commission for their continuous support, helping us reach this significant milestone, as well as to our research collaborators who are generating an unprecedented amount of clinical evidence in the US, Europe and other regions around the globe.”

MeMed BV™ measures host-immune response proteins from a small sample of blood and applies machine learning in order to accurately distinguish between bacterial and viral infections. This provides actionable information enabling better informed antibiotic and antiviral treatment decisions. By relying on the immune response, rather than direct pathogen detection, MeMed BV™ complements conventional technologies, allowing rapid and accurate diagnosis even when the infection site is inaccessible. MeMed BV™ has been validated by an unprecedented level of high-quality real-world data from over 15,000 patients and multinational, double-blind clinical studies, published in leading peer-reviewed journals, showing over 90% sensitivity and specificity (NPV>98%) across multiple pathogens.<sup>1-5</sup>

[MeMed Key™](#) is a cutting-edge technology platform that allows highly sensitive and rapid measurements of multiple proteins at the point of need, and specifically it runs MeMed BV™ within 15 minutes.

“The CE Mark clearance of our MeMed Key™ instrument marks an exciting milestone that builds on years of development work,” **said Kfir Ovid, MeMed’s co-founder, CTO and Chairman.** “The MeMed Key™ platform is not only paving the way for wide implementation of the MeMed BV™ test, but also opens the way to highly sensitive, rapid and multiplexed protein measurements at the point of care, which, so far, was mainly available using expensive central lab equipment. Leveraging the MeMed Key™ platform will allow us to expand our host-response test pipeline to other indications outside infectious diseases, furthering our efforts to continue addressing big clinical dilemmas and areas of unmet need. We are now expanding our partnerships to make these technologies widely available.”

**Professor Louis Bont, MD, PhD, Division of Pediatric Immunology and Infectious Disease, University Medical Center, Utrecht, the Netherlands, noted:** “While traditional diagnostics focus on identifying the disease-causing viruses or bacteria, this technology works differently. It identifies whether the patient’s immune system is actively fighting a bacterial or viral infection. Our international, double-blind study conducted and published in *Lancet ID*<sup>1</sup> and *BMJ Paediatrics*<sup>5</sup>, as well as studies by others, showed that this host-response solution enables more accurate diagnoses compared to today’s routine tests and will

meaningfully aid clinicians in improving antibiotic treatment decisions. This diagnostic is an essential step in our collaborative fight against antimicrobial resistance."

In addition to the CE Mark in Europe, MeMed has received AMAR clearance from the Israeli Ministry of Health to market and sell MeMed BV™ and MeMed Key™.

### **About MeMed**

Our mission is to translate the immune system's complex signals into simple insights that transform the way diseases are diagnosed and treated, profoundly benefiting patients and society. For additional information on MeMed, please visit <http://www.me-med.com>.

### **About MeMed BV™**

MeMed BV™ is a pioneering immune-based protein signature test, developed and validated over the course of decade-long collaborations with leading academic and commercial partners. It provides physicians with an indispensable tool to distinguish between bacterial and viral infections and address key clinical dilemmas with over 90% sensitivity and specificity (NPV>98%) across multiple pathogens, times from symptom onset and irrespective of colonizers.<sup>1-4</sup> MeMed BV™ measures and computationally integrates the levels of three immune system proteins: TRAIL, IP-10 and CRP. When run on the MeMed Key™ instrument platform, the MeMed BV™ test provides a result within 15 minutes. MeMed BV™ has been validated by an unprecedented level of high-quality clinical data from more than 15,000 patients and multinational, double-blind clinical studies, which have been published in leading peer-reviewed journals (including [Pediatrics](#), [The Lancet ID](#), [PLOS One](#), [BMJ Peds](#) and [European Journal of Clinical Microbiology & Infectious Diseases](#)). The MeMed BV™ test has received a CE Mark in Europe and AMAR clearance from the Israeli Ministry of Health.

### **About MeMed Key™**

MeMed Key™ is a first-of-its-kind technology platform, enabling highly sensitive measurements of multiple proteins, within minutes, at the point of need. It opens the way to quantification of a vast array of human proteins in healthy and disease states, where and when it actually matters. The MeMed Key™ development program has been partially funded by the US Department of Defense and the EU Commission. MeMed Key™ has received a CE Mark in Europe and AMAR clearance from the Israeli Ministry of Health.

### **MeMed Contacts:**

*Media:* Adee Mor, VP Marketing, MeMed

[pr@me-med.com](mailto:pr@me-med.com)

*IR:* Kfir Emmer, VP Finance, MeMed

[kfir.emmer@me-med.com](mailto:kfir.emmer@me-med.com)

Phone: +972-4-8500302

### **References**

1. Oved, K. *et al.* A Novel Host-Proteome Signature for Distinguishing between Acute Bacterial and Viral Infections. *PLoS ONE*, e0120012 (2015).

2. van Houten, C. B. *et al.* A host-protein based assay to differentiate between bacterial and viral infections in preschool children (OPPORTUNITY): a double-blind, multicentre, validation study. *Lancet Infect Dis* (2016).
3. Srugo, I. *et al.* Validation of a Novel Assay to Distinguish Bacterial and Viral Infections. *Pediatrics*
4. Ashkenazi-Hoffnung, L. *et al.* A host-protein signature is superior to other biomarkers for differentiating between bacterial and viral disease in patients with respiratory infection and fever without source: a prospective observational study. *Eur. J. Clin. Microbiol. Infect. Dis.* (2018).
5. van Houten, C, *et al.* Update of a clinical prediction model for serious bacterial infections in preschool children by adding a host-protein-based assay: a diagnostic study. *BMJ Paediatrics Open* (2019).