ZHIVAS CO. LTD.

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MANUFACTURER'S DECLARATION

TO WHOM IT MAY CONCERN,

WE, ZHIVAS LTD – Sofia, BULGARIA declare that our medical device **OXISEPT,** intended for high-level disinfection of invasive and non-invasive medical instruments and medical devices, is undergoing a new certification under the new MDR Regulation. The technical file is submitted to our new auditing body 3EC – Slovakia (CE2265), on the 19th of May 2025. This follows the Triparty agreement No: SK-0729-MDR-2/23 (pg. 10 – related to Oxisept) signed by SGS-Belgium (CE1639), 3EC-Slovakia and Zhivas ltd..

We hereby declare, based on the period needed for certification of our already certified medical devices, that we should obtain a new CE certificate for Oxisept in the second half of August 2025.

Sofia, 20.05.2025

Damiano Kamburov,
Managing Director

[redacted]
(signature)

ZHIVAS Co. Ltd. SOFIA