ZHIVAS LTD

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EU DECLARATION OF CONFORMITY

WE,	**ZHIVAS LTD – Sofia, BULGARIA** **SRN: BG-MF-000019745**
Registration:	**36, Dondukov Blvd., 1000, Sofia, BULGARIA**
Office and Production site:	**14, Assen Yordanov Blvd., 1592, Sofia, BULGARIA**
Phone:	**(+359 2) 981 78 23**
Fax:	**(+359 2) 980 25 07**
E-mail:	**zhivas@techno-link.com**
declare under our sole responsibility that the medical device:	**Oxisept,** in packages of 1 kg, 3 kg and 5 kg is in class IIb, and meets the requirements of Directive 93/42 EEC for medical devices **Basic UDI-DI: 3800228240134W**
Intended purpose:	Granulated concentrade for high-level disinfection of invasive and non-invasive medical instruments, thermo-sensitive and thermo-resistant medical devices
Applied normative documents:	**ISO 13485:2016, ISO 14971:2019** **EN 14561, EN 14562, EN 14348, EN 14476,** **EN 17126, EN 13624, EN 13727, EN 14563**

Conformity assessment procedure:

ANNEX IX "Conformity assessment based on a QMS", certificate **No M-0559/23** issued by 3EC International and certificate **No BG19/871876** of Notified Body SGS (1639).

Notified body: **SGS Belgium NV, Noorderlaan 87, 2030 Antwerp, Belgium, registered No BE0404 882 750**

CE 1639

ZHIVAS LTD keeps technical files to ensure and evaluate the conformity of the respective medical devices.

Sofia, 08.12.2023

Damian Plamenov Kamburov, Managing Director: [redacted]

(signature)

ZHIVAS Co. Ltd. SOFIA