

EC Certificate Full Quality Assurance System: BG09/76903

The management system of

# Zhivas Ltd

36, Dondukov Blvd., 1000 Sofia, Bulgaria

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 14 May 2018 until 27 February 2023  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 23 January 2021  
Issue 1. Certified since 27 February 2009

Certification is based on reports numbered BG/SOF220645

This is a multi-site certification.  
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

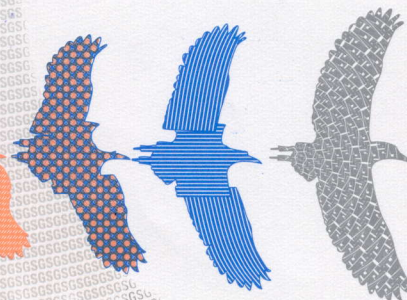
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## Zhivas Ltd

### Directive 93/42/EEC on medical devices, Annex II (excluding section 4)

Issue 1

Detailed scope

**Chemical disinfectants intended for disinfection of non-invasive medical devices including:**  
**Aldequat MD – aldehyde concentrated disinfectant**  
**Quartysept – for disinfection of medical devices**  
**Zhivahex Concentrate 5 % MD - chlorhexidine based concentrated disinfectant (used for non-invasive devices)**

**Chemical disinfectants intended for disinfection of invasive medical devices including:**  
**Citricadez - Citric acid based liquid concentrate disinfectant**  
**Zhivahex burbath - ready for use disinfectant for small rotative stomatological instruments**  
**Zhivahex spray MD - alcohol based ready to use disinfectant**  
**Septoquat AM MD - concentrate based on QUATS and alkylamine disinfectant & Septoquat AM MD RFU**  
**Oxisept - active oxygene based concentrated powder disinfectant**  
**Glutasept S - aldehyde based ready to use disinfectant**  
**Aldesept MD - aldehyde based concentrated disinfectant**  
**ENZYDIP-3 AM for enzymatic cleaning and disinfection of medical devices**  
**Glutarquat MD for disinfection of medical devices**  
**ZHIVASEPT RAPID MD for disinfection of medical devices**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

**14 Asen Yordanov Blvd., (Chimatech Building), 1592 Sofia, Bulgaria**