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EC Certificate Full Quality Assurance System: Certificate BG19/871876

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 12 May 2021 until 27 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 27 February 2009

Certification is based on reports numbered BG/SOF 220645

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

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Zhivas Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

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 for disinfection of medical devices (used for disinfection of haemodialysis machines)
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, Assen Yordanov Blvd, (Chimatech Building), 1592 Sofia, Bulgaria