

EC Certificate Full Quality Assurance System: GB09/76903

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 09 July 2015 until 27 February 2020 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 23 January 2018 Issue 6. Certified since 27 February 2009

Certification is based on reports numbered GB/PI 220645

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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EC Certificate Full Quality Assurance System: GB09/76903, continued

Zhivas Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 6

Detailed scope

Chemical disinfectants for disinfection of invasive and non-invasive medical instruments and medical devices, cold chemical disinfection of heat-resistant and heat-sensitive 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

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