3EC International

3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2026-MDR/QS-058

Zhivas Ltd.

Registered address: 36, Dondukov Blvd., 1000 Sofia, Bulgaria
Production site: 14, Assen Yordanov Blvd., 1592 Sofia, Bulgaria
SRN No.: BG-MF-000019745

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

Disinfectant
For models/variants, see Annex I
Intended purpose: see Annex II
MD class IIb
(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the Technical Documentation Assessment Report No. MDR237_2023 from 2026-08-31, Clinical Evaluation Report No. MDR237_2023 from 2026-08-31 and Audit Report No. SK-0729-26 from 2026-09-18. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Valid from: **2026-09-22**
Valid until: **2028-11-10**
First issue: **2026-09-22**
Revision: **0**
History: **See Annex III**

In Bratislava, Slovak Republic, 2026-09-22

3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

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ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-MDR/QS-058

issued for the company

Zhivas Ltd.

Registered address: 36, Dondukov Blvd., 1000 Sofia, Bulgaria
Production site: 14, Assen Yordanov Blvd., 1592 Sofia, Bulgaria

List of medical devices covered by the EU Quality Management System Certificate:

MD Name	Trade Name	Alternative Trade Names	Packaging
Disinfectant	Aldesept MD	N/A	250 ml, 1L, 3L and 5L

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-09-22
Valid until 2028-11-10

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ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-MDR/QS-058

issued for the company

Zhivas Ltd.

Registered address: 36, Dondukov Blvd., 1000 Sofia, Bulgaria
Production site: 14, Assen Yordanov Blvd., 1592 Sofia, Bulgaria

Intended purpose of medical devices covered by the EU Quality Management System Certificate:

Aldehyde based concentrate for high-level disinfection of reusable invasive and non-invasive medical instruments and medical devices.

Notified body
BEC International
NB 2265
NOTIFIKOVANÁ OSOBA

Katarina Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-09-22
Valid until 2028-11-10

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-MDR/QS-058

issued for the company

Zhivas Ltd.

Registered address: 36, Dondukov Blvd., 1000 Sofia, Bulgaria
Production site: 14, Assen Yordanov Blvd., 1592 Sofia, Bulgaria

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
0	2026-MDR/QS-058	2026-09-22	MDR237_2023	Initially issued certificate

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-09-22
Valid until 2028-11-10

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