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DECLARATION OF CONFORMITY

WE,

ZHIVAS LTD – Sofia, BULGARIA

Head Office: 36, Dondoukov Blvd., 1000, Sofia, BULGARIA
Postal and factory address: 14, Assen Jordanov Blvd., 1592, Sofia, BULGARIA
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declare under our sole responsibility

that the medical device ENZYDIP-3 AM

meets all the provisions of DIRECTIVE 93/42/EEC, which apply to it.

Applicable standards: ISO 13485:2012, ISO 14971:2012,
EN 14561:2006, EN 14562:2006 ,

Additional information: The Medical device described above is in **Class IIb** according to the rules of **Annex IX of DIRECTIVE 93/42/EEC**.

Conformity assessment procedure: **ANNEX II “Full Quality Assurance System”** and based on certificates No **GB09/76902** and **GB09/76903** of Notified Body **SGS (0120)**

Notified body: **SGS United Kingdom Ltd., Systems & Services Certification, 202B, Worle Parkway, Weston-super-Mare, BS22 6WA, UK**



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

Sofia, 07.01.2016

Plamen Damianov Kamburov, Managing Director

(signature)