

1504 София, бул. Янко Сакъзов 26  
 Факс: \*\*359 2 943 34 55  
 Телефон Управител:  
 \*\*359 2 944 61 91  
 E-mail: bulbio@bulbio.com

1504 Sofia, 26 Yanko Sakazov  
 blvd. Fax: \*\*359 2 943 34 55  
 Telephone General Manager:  
 \*\*359 2 944 61 91  
 E-mail: bulbio@bulbio.com

## CERTIFICATE

### FOR QUALITY CONTROL

Diluent (Saline) for BCG Vaccine

Sol.inj., amp. – 1.0 ml, x 20

Lot № 391 – 1

<i>Type of controls</i>	<i>Standard</i>	<i>Results</i>
Appearance	Colourless transparent liquid	Passes
Extractable volume	≥ 1.0 ml	Passes
pH	5.00 – 7.00	6.47
Sodium Chloride	0.65 – 1.15 %	0.89 %
Sterility	Sterile	Passes
Pyrogens	≤ 1.15 °C (if summed response of three rabbits does not exceed)	+ 0.2 °C

Date of manufacture: April 2016

Expiry date: March 2021


**CONCLUSION:**

Diluent (Saline) for BCG Vaccine Lot № 391-1 meets European Pharmacopoeia requirements.

The product has been produced in a firm with approved Quality Management System Standard: ISO 9001:2008

Date of issue: 25.04.2016

Head of Quality Control Department:

  
 J. Cenkova, MD