



Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,**  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## EC Design-Examination Certificate

### No. 17 0125 CN/NB

issued for manufacturer

**Delta Biologicals s.r.l.**

**Via Nicaragua 12-14, 00071 Pomezia (Roma), Italy**

in accordance with requirements of

**Directive 98/79/EC**

**on in vitro diagnostic medical devices, Annex IV (4)**

for the following product category(ies):

**HBe Ag & Ab**

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive.

**Valid from:** 2017-03-17


**Valid until:** 2022-03-16

**First Issued:** -

**Revision:** -

Date: 2017-03-17



  
RNDr. Radomír Čevelík  
Representative of the Notified Body No. 1023



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## Annex to EC Design-Examination Certificate

**No. 17 0125 CN/NB**

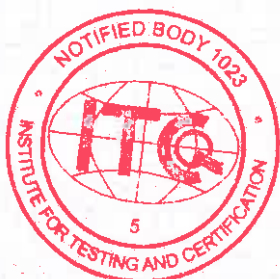
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### Product:

<b>Name:</b>	<b>HBe Ag &amp; Ab</b>
<b>Trade name(s):</b>	HBe Ag & Ab
<b>Model(s):</b>	HBe Ag & Ab 96 test
<b>Classification:</b>	List A
<b>GMDN:</b>	36017

Date: 2017-03-17  
Revison: -



  
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### Certificate History:

Revision	Date	Reference Number	Action
	2017-03-17	813600546	Certification – conformity assessment process of IVD kit HBe Ag & Ab

Date: 2017-03-17  
Revision: -



  
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