



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

## EC Certificate - Full Quality Assurance System No. 17 0127 QS/NB

The quality system of manufacturer

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

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

has been certified as meeting the requirements of

**Directive 98/79/EC**

**on in vitro diagnostic medical devices, Annex IV excluding (4, 6)**

for the following product category(ies):

**In vitro diagnostic kits for detection HBV, HCV and HDV**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to Annex IV (Section 4) is required.

**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 Certificate No. 17 0127 QS/NB**  
issued for manufacturer:

**Delta Biologicals s.r.l.**  
**Via Nicaragua 12-14, 00071 Pomezia (Roma), Italy**

**Product(s):**

**Name:** HDV Ab  
**Trade name(s):** HDV Ab  
**Model(s):** HDV Ab 96 test  
**Classification:** List A  
**GMDN:** 30750

**Name:** HDV Ag  
**Trade name(s):** HDV Ag  
**Model(s):** HDV Ag 96 test  
**Classification:** List A  
**GMDN:** 30747

**Name:** HDV IgM  
**Trade name(s):** HDV IgM  
**Model(s):** HDV IgM 96 test  
**Classification:** List A  
**GMDN:** 30752

**Name:** HBsAg One Step  
**Trade name(s):** HBsAg One Step  
**Model(s):** HBsAg One Step 96 test  
HBsAg One Step 192 test  
**Classification:** List A  
**GMDN:** 30723

Date: 2017-03-17  
Revision: -



*Paul Vp*  
RNDr. Radomír Čevelík  
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**Name:** HBs Ab  
**Trade name(s):** HBsAb  
**Model(s):** HBsAb 96 test  
**Classification:** List A  
**GMDN:** 30725


**Name:** HBc Ab  
**Trade name(s):** HBcAb  
**Model(s):** HBcAb 96 test  
**Classification:** List A  
**GMDN:** 30731

**Name:** HBc IgM  
**Trade name(s):** HBc IgM  
**Model(s):** HBc IgM 96 test  
**Classification:** List A  
**GMDN:** 30733

**Name:** HBe Ag & Ab  
**Trade name(s):** HBe Ag & Ab  
**Model(s):** HBe Ag & Ab 96 test  
**Classification:** List A  
**GMDN:** 36017

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Revision: -



  
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**Name:** HCV Ab  
**Trade name(s):** HCV Ab  
**Model(s):** HCV Ab 96 test  
**Classification:** List A  
**GMDN:** 30743

**Facility(ies):**

Delta Biologicals s.r.l.  
Via Nicaragua 12-14, 00071 Pomezia (Roma), Italy

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## Annex to EC Certificate No. 17 0127 QS/NB

issued for manufacturer:


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

### Certificate History:

Revision	Date	Reference Number	Action
	2017-03-17	813600545 813600546	Certification – conformity assessment process of IVD kits HDV Ab, HDV Ag, HDV IgM, HBsAg One Step, HBs Ab, HBc Ab, HBc IgM, HBe Ag & Ab and HCV Ab

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Revision: -



  
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