



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

Date: 2017-03-17
Revision: -



Paul Uš
RNDr. Radomír Čevelík
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issued for manufacturer:

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


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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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

Date: 2017-03-17
Revision: -




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