
Date: 28 August 2023

CLARIFICATION NOTE #2

Reference: ITB/SEC/16/2023

Subject: Supply and delivery of laboratory reagents and consumables for veterinary labs in Ukraine

In accordance with issued **ITB/SEC/16/2023**, the OSCE would like to provide the following clarification to the ITB documents.

1) **Question 1:**

For the authorization - does it have to be direct from the manufacturer or can it be from their authorized representative?

Answer 1:

It can be either from the manufacturer or from the authorized official distributor.

2) **Question 2:**

There is a requirement to attach certificate/declaration of conformity for the offered products. Some of the listed products are not medical devices, and as such they do not have declarations of conformity.

Each lot is accompanied by a certificate of analysis, but other than that, the detailed specifications and performance data for the products are usually listed in the IFU.

Will it suffice to provide relevant product literature verifying the listed specifications, even if it is not under the title of certificate of conformity?

Answer 2:

A declaration of conformity (DoC) is a document to declare that the products comply with the applicable requirements (in which the manufacturer specifies which directives and standards his product complies with). This should apply not only to medical devices.

DoC can be issued by the manufacturer as well as by an authorized representative.

A certificate of analysis is suitable to replace the DoC where the DoC cannot be provided.

3) **Question 3:**

We have one scientific question: why do you need endogenous and internal control as these two parameters are going to make the kits expensive and of no scientific use, however you can ask one of these controls as they will give also equally good results?

Answer 3:

Indeed, in LOT 5 for all 6 positions we have a bullet referring to internal and endogenous control. This should be considered as one requirement for internal control. You can provide one of these controls.

Sincerely,

Dmytro Agapov,
Associate Procurement Officer,
OSCE Secretariat