# Procurement of Medical Devices for the Clinic for Neurosurgery - Clinical Centre of Serbia

## NO. IOP/12-2018/RD

## Clarification no. 1

## Issued on July 9, 2018

**Question 1**

"On the pages 57 and 58 of tender documents, it says: ""2.2. The equipment offered should be manufactured in compliance with Quality Standard ISO 9001 certification for Manufacturer(s) and Service company."" Majority of renewed medical equipment manufacturer maintain Quality Management System complying with ISO 13485. ISO 13485 was designed on basis of ISO9001, but specifically for the product scope of medical devices and is even more restrictive. Is it allowed to submit ISO 13485 instead ISO9001?"

**Answer 1**

Yes, ISO13485 is acceptable.

**Question 2**

"On the pages 57 and 58 of tender documents, it says: ""2.2. The equipment offered should be manufactured in compliance with Quality Standard ISO 9001 certification for Manufacturer(s) and Service company."" Majority of renewed medical equipment manufacturer maintain Quality Management System complying with ISO 13485. ISO 13485 was designed on basis of ISO9001, but specifically for the product scope of medical devices and is even more restrictive. Is it allowed to submit ISO 13485 instead ISO9001?"

**Answer 2**

Yes, ISO13485 is acceptable.

**Question 3**

We kindly ask you for confirmation of whether the documents such as catalogs, brochures, instruction for use, manufacturer's statement as a proof technical characteristics can be submitted as copies and extracts or do we have to submit the original documents?

**Answer 3**

All abovementioned documents can be submitted as copies.

**Question 4**

Under financial capability requirements the purchaser request a certificate that the bidder did not have any registered blockage of their account from the beginning of 2017. Since these data are publicly available is it acceptable for the purchaser that the bidders with Serbia as place of

registration submit an excerpt from the official webpage of NBS where that data on account blockage are publicly available for the period of past 3 years?

**Answer 4**

Yes, it is acceptable.

**Question 5**

In Technical specifications for Position 7.3 - Intense care hospital bed (Sheet Intense2) in ID 4 it says - ""Electrical height adjustment in the minimum range of 400 to 800 mm""

We are kindly asking you to allow participation to potential bidders with the bed that has electrical height adjustment range 485-885 mm. This will not influence practicality of bed usage, as the movement range from the lowest to the highest point remains 400 mm, as it was demanded.

**Answer 5**

Yes, it is acceptable.

**Question 6**

In Technical specifications for Position 7.3 - Intense care hospital bed (Sheet Intense2) in ID 16 it says - ""Shank rest segment adjustment min. 25° by gas spring or better""

We are kindly asking you to allow participation to potential bidders with the bed that has shank rest segment adjustment 24° by gas spring. That is only 1° difference that will not influence quality of the equipment."

**Answer 6**

Yes, it is acceptable.

Public Procurement Committee

Jelena Simić