**Procurement of Medical Devices for University Children Hospital "Tiršova"**

**IOP/11-2017/RD**

**Clarification no. 13**

**Issued on December 7, 2017**

**Question 1:**

By the tender documentation on page 61, Purchaser has defined ISO 9001 certification for Quality Control Standards, for all manufacuterers. Is it acceptable to Purchaser ISO 13485 for manufacturing and distributing medical devices that obtain principles and standards of ISO 9001?

**Answer 1:**

**ISO 13485 is acceptable.**

Question 2:

Is it acceptable to submit confirmation of technical specification issued by European representative of the manufacturer in the case that all requested characteristics can not be found in the brochure or technical data?

**Answer 2:**

**It is acceptable.**

Question 3:

Tender documentation, Section (e) Technical Capability: It is requested that "Manufacturers - shall provide after sales service for equipment by the service company registered in the Republic of Serbia."

In the next section, the following Documentary evidence is requested for this capability: Excerpt from register of the relevant authority, which proofs that Bidder is registered with the competent body, or entered in the appropriate register.

Can you please clarify if this Documentary evidence must be provided for the Service company rather than for the Bidder.

**Answer 3:**

**Documentary evidence must be provided for the Service company.**

**It is technical error in Tender documentation.**

Public Procurement Committee