

**Procurement of Medical Devices for the Obstetrics and Gynaecology Clinic
“Višegradska” - Clinical Centre of Serbia**

IOP/18-2018/RD

Issued on August 24, 2018

Question 1

Can you please answer to us regarding requested ISO 9001 certificate for the manufacturer.

ISO 9001 certificate specifies the minimum requirements for a quality management system (QM system), where an organization has to meet in order to provide products and services which meet customer expectations and any regulatory requirements. Since ISO 13485 certificate represents the requirements for a comprehensive management system for the design and manufacture of medical devices, and includes the requirements of ISO 9001 (ISO 13485 contains detailed requirements on issues relating to the production and marketing of medical devices and in particular to product safety) , can you please confirm that it will be acceptable to submit ISO 13485, instead ISO 9001 for the Manufacturer?

Answer 1

Yes, ISO13485 is acceptable.

Question 2

With reference to the Section II BDS-C ITB10.1 (page 27), please clarify if the Serbian Bidder is obliged to provide translation to English language of all the documents issued by the Serbian authorities, envisaged in post-qualification requirements p. 34-37 of the Tender Documents, with the aim to confirm the Bidder's legal, financial and technical capability to participate at the Tender and perform the Contract.

Answer 2

Language for translation of supporting documents/documentary evidences and printed literature is English or Serbian, except for documents and evidences made in Serbian or issued by the relevant authority in Serbian language. It is not necessary to provide translation to English language for documents issued by Serbian authorities.