

## **Clarification**

**17-11-2018**

Sub: Clarification to the Bidding Document

Ref: Notice Inviting Bid ref. HITES/PCD/NCI-AIIMS/34/18-19 dated 26.09.2018 read with its Amendments No. 1 and 2 dated 20.10.2018 and 09.11.18 respectively.

The following clarification has been authorised and is being incorporated in the above referred Bidding Document.

*Clarification:*

**"It is clarified that wherever 'European CE/ European CE with 4 digit notified body number' has been asked for, the certification must be obtained as per the procedure prescribed under 93/42/EEC Medical devices directive."**

**In case of bidder is submitting self-declaration of conformity for class 1 products, it has to be submitted along with ISO 13485.**

All other contents of the Bidding Document including terms & conditions remain unaltered.