**Q.1 We would very much like to respond to the RFP, but on examination I’ve seen you require manufacturers to be ISO13485 certified – we are working towards this but currently do not have it. We do have CE and UK CA marks and are just in the process of updating our declaration of conformity from the MDD to the MDR but do not yet have an ISO accredited QMS. Could we still be considered as a manufacturer/supplier without ISO 13485 certification?**

A.1 All submissions will be considered and evaluated. On an exceptional basis, it is possible for a quality certification uncompliant supplier to be chosen under adequate justification.

**Q.2 How long will the approved list of manufacturers/suppliers from this RFP be in place for?**

A.2 As per section 3. Term on page 16 on the RFP document the proposed LTA-G shall be valid for an initial period of twenty-four (24) months, with a possible renewal for an additional period of twelve (12) months.

**Q.3. If we cannot currently be considered as a manufacturer/supplier without ISO 13485 certification would we be able to apply once we receive certification?**

A.3 Please, refer to A.1.

**Q4. Section D, No 20: From where can I refer UN hazardous clarification code? Any document to refer to this number?**

A.4 A UN number is a four-digit number that identifies dangerous goods, hazardous substances and articles (such as explosives, flammable liquids, toxic substances, etc.) in the framework of international transport. They are assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods.

**Q.5 Sheet 170, Section G, no 41, our device has manual focus and not autofocus, how can we specify that. If we select no as an option, that will convey that both auto and manual focus are not there.**

A.5 In case the product does not have both, the answer should be "No". The existence of only manual or auto-focus can be mentioned in the question G-69.