|  |  |
| --- | --- |
| **Reference**  (to be completed NEOEMKI) |  |
|  |

**Quotation Request Questionnaire for the certification**

**of Quality Management System according to standards EN ISO 9001, EN ISO 13485**

**1.) Data of manufacturer’s registered office:**

|  |  |
| --- | --- |
| **Name** |  |
| **Address** |  |
| **E-mail address & website** |  |
| **Phone/Fax** |  |
| **Postal address** (when different) |  |
| **Tax identification number** |  |
| **Registration №** |  |
| **CEO** |  |
| **contact** (e-mail or phone) |  |
| **Activity** (See section 3. for more than one sites) |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Contact person (I)** | **Contact person (II)** |
| **Name** | |  |  |
| **Position** | |  |  |
| when different | **Address** |  |  |
| **E-mail address** |  |  |
| **Phone / Fax** |  |  |

**2.) Authorized representative:**

**(Authorized by manufacturers OUTSIDE the EU):**

|  |  |
| --- | --- |
| **Name** |  |
| **Address** |  |
| **E-mail address** |  |
| **Phone number/Fax** |  |
| **Postal address (if diff.)** |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Contact person (I)** | **Contact person (II)** |
| **Name** | |  |  |
| **Position** | |  |  |
| when different | **Address** |  |  |
| **E-mail** |  |  |
| **Phone /fax** |  |  |

**3.) Details of further manufacturing sites:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Cert.¹** | **Address** | **Activity** | **№ of staff** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**¹**Please sign with X if the site is requested to be included in the certificate.

**4.) Outsourced activities** (key subcontractors, critical suppliers**):**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of the contractor** | **Address** | **Activity** | **Type of certification possessed** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**5.) Details of processes of production**, or **service activities** (flow chart can be attached):

|  |  |  |  |
| --- | --- | --- | --- |
| **Process** | **Applied technology** | **Name of supplier / manufacturing site** (with number of employees) | **Number of employees**  **(in activities ratio)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**6.) Details of medical device manufactured or services related to medical device**

|  |  |
| --- | --- |
| **Product(family)** or **service provided** | **Medical Device function of products concerned, classification** |
|  |  |
|  |  |
|  |  |
|  |  |

**7.) Previous certifications** (Please, also indicate certifications expired):

|  |  |  |  |
| --- | --- | --- | --- |
| **Notified Type** (e.g. ISO 9001) | **Certification / Notified Body** | **Certification Scope** | **Validity period** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**8.) Details of requested certification:**

|  |  |
| --- | --- |
| **Required deadline of quotation** |  |
| **Intended date of certification:** (only systems operated at least for 3 months previously can be certified) |  |
| **Application of external consultant for introducing management system:\***  **Firm / Name** |  |
| **How did you get any information about certification activity of EMKI:\*** | **Internet  Media  Business partner**  **Other: ........…………………………………….** |

**\***It is not compulsory to fill in.

**9.) System certification according to EN ISO 9001:2015:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scope of certification:** | | | | | | |
| **Not applications:** |  |  |  |  |  |  |
| **Number of employees under certification scope per shifts:** | **Shift 1.** |  | **Shift 2.** |  | **Shift 3.** |  |
| **Number of copies and the languages of required certificates:** | | | | | | |

**10.) System certification according to EN ISO 13485:2016:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scope of certification:** | | | | | | |
| **Exclusions: (only from chapter 7. of the standard)** |  |  |  |  |  |  |
| **Sections “Not Applied” of the standard** |  |  |  |  |  |  |
| **Number of employees under certification scope per shifts:** | **Shift 1.** |  | **Shift 2.** |  | **Shift 3.** |  |
| **Number of copies and the languages of required certificates:** | | | | | | |

**Date:**

official signature

Name and position of signatory *(print, please)*: