| Company: | | | | | enter company name | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | | | |
| We will shortly perform a surveillance audit at your company. Please inform us about the current circumstances regarding your company and/or processes by replying to the following questions. | | | | | | | | | | | | | |
| **In case you answer any of the below listed questions with “yes,” please complement your answer by using the comments field (section 7) for supplying more detailed information, and/or attach additional information.** | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **EC Directives** | | **UK MDR** | | | | | | **(EN) ISO 13485** | | **MDSAP** | | | |
|  | | | | | | | | | | | | | |
| **1.** | **Processes / Product Groups** | | | | | | | | | | | **Reply** | |
| 1.1 | Did the existing processes undergo any significant changes? | | | | | | | | | | | yes | no |
| 1.2 | Have new processes been introduced? | | | | | | | | | | | yes | no |
| 1.3 | Have any processes been cancelled? | | | | | | | | | | | yes | no |
| 1.4 | Have new product groups been introduced? | | | | | | | | | | | yes | no |
|  | | | | | | | | | | | | | |
| **2.** | **Employees / Sites** | | | | | | | | | | | **Reply** | |
| 2.1 | What is the current number of employees in the scope of the certificate? | | | | | | | | | | | employees | |
| 2.2 | Please indicate the number of employees per site:        Employees, site        Employees, site        Employees, site | | | | | | | | | | |  | |
| 2.4 | Have new sites been added or existing sites been cancelled? | | | | | | | | | | | yes | no |
|  | | | | | | | | | | | | | |
| **3.** | **Cover Letters** | | | | | | | | | | | **Reply** | |
| 3.1 | New issue of TCP cover letter? | | | | | | | | | | | yes | no |
| 3.2 | New issue of Ukraine cover letter? | | | | | | | | | | | yes | no |
|  | | | | | | | | | | | | | |
| **4.** | **Products (only applicable for products in the scope of certificates based on EC Directive/UK MDR)** | | | | | | | | **Reply**  **(EC Directive)** | | | **Reply**  **(UK MDR)** | |
| 4.1 | Are there any products that underwent any significant changes? | | | | | | | | yes | | no | yes | no |
| 4.2 | Have new products been introduced? | | | | | | | | yes | | no | yes | no |
| 4.3 | Have any products been cancelled from the product portfolio? | | | | | | | | yes | | no | yes | no |
|  | | | | | | | | | | | | | |
| **5.** | **Incidents / Feedback (only applicable for products in the scope of certificates based on EC Directive/UK MDR)** | | | | | | | | **Reply**  **(EC Directive)** | | | **Reply**  **(UK MDR)** | |
| 5.1 | **MDD:** Have there been any serious incidents and/or field safety corrective actions as defined in MDR, Art. 87, and/or trend reports as defined in MDR, Art. 88?  **IVDD:** Have there been any reportable incidents and/or field safety corrective actions?  **UK MDR:** Have there been any incidents and/or field safety corrective actions? | | | | | | | | yes | | no | yes | no |
| 5.2 | Has there been any feedback from the market resulting in recommendations regarding measures (e.g. feedback from competitors recommending field safety corrective actions (FSCA))? | | | | | | | | yes | | no | yes | no |
| 5.3 | Has there been any feedback from the market resulting in significant product changes? | | | | | | | | yes | | no | yes | no |
| 5.4 | Have there been any queries from authorities regarding conformity of certified processes or the safety of certified products? | | | | | | | | yes | | no | yes | no |
|  | | | | | | | | | | | | | |
| **6.** | **Significant Change Notifications** | | | | | | | | **Reply**  **(EC Directive)** | | | **Reply**  **(UK MDR)** | |
| 6.1 | Did you already submit any Significant Change Notifications to TÜV Rheinland LGA Products GmbH/TUV Rheinland United Kingdom Ltd. regarding the above listed items? | | | | | | | | yes | | no | yes | no |
|  | | | | | | | | | | | | | |
| **7.** | **Comments** | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
|  | | |  | YYYY-MM-DD | |  |  | | | | | | |
| Place | | |  | Date | |  | Completed by <name and function>  (contact person to verify the provided information, if needed) | | | | | | |