***Dear Certificate Holder – Hoya Medical Singapore Pte Ltd ,***

In preparation for the upcoming audit, we would like to ask you for your support to know about the current situation of your company. Attached please find your current **Application Appendix A/B/C** for all applicable schemes, which reflects the approved content of our certification data base.  
Please use this form as a tool for updating the **Application Appendix A/B/C** and providing necessary documents and information. Corrections to information can be made directly in each **Application Appendix A/B/C** document; when changes are made in the Application Appendix A/B/C, please change the background of all changed cells to yellow. Information that is not relevant to you has been crossed out, so to ensure that you do not miss anything, please scroll through to the end of this form.

For all changes which do not require a formal **Change Notification (Application including Appendix D)**, please document the changes within the provided **Application Appendix A/B/C** change the background of all changed cells to yellow.   
**Note**: How to change the background of the changed cell to yellow: Click on the cell that is being changed. In the “Home” ribbon go to the “Font” group, click on “Fill Color” and select yellow.

In case of significant changes*,* please complete and send to us a formal **Change Notification (Application including Appendix D)**.

***Note on language:*** *All submitted documents and the responses within this form shall be in English.*

|  |  |
| --- | --- |
| **Audit Date Confirmation** | **Confirmed** |
| Please be informed your annual audit target date is [month, day].  For surveillance audits there is a target tolerance of -3/+1 from the audit target date.  For recertification audits there is a target tolerance of -3/+0 from the audit target date.  If the audit is not performed within the identified target / tolerance period, your certificate could be at risk of suspension or expiration. | |

**Application Appendix A/B/C - General Information**

Please complete the following checks for each applicable Application Appendix A/B/C.

1. **Appendix A –**

If additions or deletions are required, please ensure changes are made in a manner that ensures reference integrity between the product/device list, site list, and critical supplier list (e.g., make any additions at the bottom of the existing list, do not renumber sites/suppliers following a deletion).

|  |  |  |
| --- | --- | --- |
|  | **Done** | **NA** |
| * Please check **name and address** – they should be identical to those on the certificate(s) |  |  |
| If there are any changes in name and address, please submit a **Change Notification (Application including Appendix D)**. |  |  |
| * Check the **Device/ Product list** for **completeness** |  |  |
| * Check the **Device/ Product list** for accurate **code and grouping** assignments |  |  |
| * Check the **Device/ Product list** for accurate **device specifics and intended purpose** |  |  |
| * Check the **Device/ Product list** for accurate linkages to the associated **sites** |  |  |
| * Check the **Device/ Product list** for accurate linkages to the associated **critical suppliers** |  |  |

1. **Appendix B Facilities**

|  | **Done** | **NA** |
| --- | --- | --- |
| * Please submit a current Organizational Chart |  |  |
| * Check the **name and address** of each **SITE** within the certified scope (if applicable) |  |  |
| * Check each site’s **Contact Person** information for accuracy |  |  |
| * Check **Processes/ Subsystems performed** at each site for conformity with the information on the certificate (**Site Specific Scope**) |  |  |
| * If there are any other significant changes (e.g., additional/deleted facilities, change in activities / processes), please submit a **Change Notification** **(Application including Appendix D)**. |  |  |
| *Table 1- Employee Headcount* |  |  |

1. **Appendix C Supplier-**

|  | **Done** | **NA** |
| --- | --- | --- |
| * Check that **Critical Suppliers** are all listed with full name and address |  |  |
| * Check that the column **Product, component, process, or service provided, or key process outsourced** clearly identifies WHAT each supplier is doing for a manufacturer |  |  |
| * Check that the field **Applicable MD regulatory schemes** is completed correctly for each supplier – it helps us with audit planning, to understand for which regions the supplier’s products/services are involved |  |  |
| * Determine whether the field “jointly visited” needs to be checked – yes if the supplier is visited jointly with this Audit Project |  |  |
| * Check that a **Justification for audit or no audit** is given for each supplier. This justification documents how the manufacturer controls its critical supplier (e.g., client controls such as incoming inspection, in process control, final control, contractual agreements etc. according to NBOG 2010-1 and other relevant QMS certifications) |  |  |
| * If there are any changes of **Critical Suppliers** (e.g., new or changed Regulatory Correspondent, Sterilization Service etc.), please submit a **Change Notification (Application including Appendix D)**. |  |  |

**Additional Information for audit preparation**

|  |  |
| --- | --- |
| **Corrective Action** | **Attached** |
| For follow-up on your corrective action plan of last audit, we need to see documented evidence for implementation.  Therefore, **please provide a list of implemented corrective actions** which should address a clear reference to documents which can be followed up during the audit. List the attached corrective action implementation list document’s name:  NA. No observations from last audit. | |
|  |  |
|  | |

**EC/EU Certification Update**

1. **FSCA reports/FSNs, recalls, product removals, replacements, other vigilance information**

Additional to the information provided by the updated Application Appendix A/B/C for proper audit planning and updating our audit program we’d like to ask for following event information based on post market surveillance:

**Since last audit there were**

|  |  |
| --- | --- |
| Number of Field Safety Corrective Action (FSCAs) / Recalls: | 1 |
| Number of Field Safety Notice (FSNs): | 0 |
| Number of vigilance reports reported to Authorities: | 0 |

**In case of any events** (see above), please **create and submit a complete list**, which includes FSCAs, FSNs and/or vigilance report information since last audit.

|  |  |
| --- | --- |
| FSCA | Description |
| ESC-003\_21 | SP2Y-GM clinical study sample IOLs shipped and used unauthorized for commercial distribution |

1. **Information requested for Unannounced Audit Planning (UAA)**

In order to properly plan the audit for each product group, please **provide the following information**:

|  |  |
| --- | --- |
| **Facilities shut down** (times of planned closure of plant / production in the next 12 months): | HOYA Lamphun – Once for period between 13-15Apr22(Songkran Festival)  HOYA Medical Singapore – All public holidays in Singapore  HOYA Medical Research Center (HMRC) – All public holidays in Japan |
| Consider also shutdowns of **outsourced** manufacturing activities / critical supplier like EC-OEM supplier or sterilization services – list as applicable: | 27-30Apr2022 for sterilization service contractor, SIS |
| **Public holidays,** annual company holiday period (related to the location of all facilities)  (if applicable): |  |
| **Other non-manufacturing periods** (when an unannounced audit is not feasible): | HLAM - 13-15Apr22(Songkran Festival)  HMSP – weekends, public holidays, and eve of public holidays  HMRC – weekends, public holidays, and eve of public holidays |

1. **Technical Documentation Assessment – Audit Planning**

To properly plan the audit and Technical Documentation Assessment, for each product group please **provide the following information**:

* Preferably, the EC-Technical Documentation should be submitted in STED format   
  (Format guidance [click here](http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n011r20-essential-principles-safety-performance-medical-devices-sted.pdf))
* The EU-Technical Documentation should be submitted in a format compliant with MDR/IVDR Annex II and Annex III.
* In preparation for the upcoming **Technical Documentation Assessment**, please provide relevant production information related to the following CE-marked device:
  + Product-ID: ***Product(s) selected by the project handler (PH) based on sampling plan***

***Example:*** *Key Production & Process Information for device/major component:*

| Process  Material/Component/ Assembly | Process  Description/Reference | Critical Supplier/  In-house | Process Control Activities |
| --- | --- | --- | --- |
| **The listing here are** | **examples only and shall be** | **replaced by real** | **key production & process information** |
| **See Technical Documentation submitted** | | | |

A usual worksheet router may be provided in case it contains the requested information, otherwise the above table can be used.

In case one sampled article consists of many different major components, please provide the worksheet routers of the major components.

E.g., The article # stands for a set of XX articles, please provide the worksheet router of the set and include the routers for > 10% of the major sub parts and/or its accessory.

E.g., The article # stands for a complex machine, please provide the worksheet router of the machine, and include the routers for the major components and/or its accessory.

1. **Planned Changes – Perlin to check with andreas**

Are there any planned changes to the topics requested above?

Yes

No

If yes, please specify:

|  |  |
| --- | --- |
| **Date of planned Change** | **Description of planned Change** |
| Please specify the planned date of the change (e.g., Dec 2020) as far as already known | Please shortly describe the change(s) and the affected products |

**Additional Information for MDSAP – Audit Planning**

In addition to providing the updated Application Appendix A/B/C, please supply the following information for proper audit planning and updating of our audit program.

Since last audit there were:

|  |  |
| --- | --- |
| Number of Complaints | 1,494 |
| Number of Adverse event reports | 191 |
| Number of Advisory notices | 0 |
| Number of Vigilance reports reported to Authorities | 191 |

**In case of any events** (see above), please **create and submit a complete list**, which includes adverse events reports, advisory notices and/or vigilance report information since last audit.

Complete list of events will be furnished separately.

Request for complaints list, and adverse event reports

* Were any new devices put on the market in Australia, Brazil, Canada, Japan or USA? If so, please identify these below or attach additional pages.

No new devices for put on markets in Australia, Canada, and USA since last audit.

|  |  |
| --- | --- |
| **Country** | **New Product Approval (Since July 2021)** |
| Australia | N/A, No new products within this period |
| Japan | “CTR130P” (which is Preloaded CTR) |
| Brazil | XY1-G, XY1-GP, XY1-GT, XY1-GPT, NC1-SP, NY1-SP |
| Canada | N/A, No new products within this period |
| USA | N/A, No new products within this period |

* Were there any new revisions to the design of devices put on the market in Australia, Brazil, Canada, Japan or USA? If so, please identify these below or attach additional pages

No new revisions to the design of devices that were put on market in Australia, Brazil, Canada, Japan and USA since last audit

|  |  |
| --- | --- |
| **Internal Audit** | **Attached** |
| Please provide the latest copy of your internal audit program or similar, indicating the scope of each of the internal audits. Please list the attached internal audit program document’s name:   * + Audit Schedule for Global Compliance Audits FY2021, revision 3, Pending completion | |

|  |  |
| --- | --- |
| **Quality Manual** | **Attached** |
| Please provide the latest copy of your Quality Manual. Please list the attached Quality Manual’s document number, revision and name:  SOP-16-001, revision 17, Global Quality Manual | |



**Thank you for your cooperation**

Please return **this document** and the **applicable Appendix A/B/C’s** together with **related information** to update our certification data base to the TÜV SÜD Project Handler/CARE.

--- END of FORM ---

Table 1- Employee Headcount

|  |  |  |  |
| --- | --- | --- | --- |
| **Employee headcount for HSO** | | | |
| **Site** | **2021** | **2022** | **# Shifts operated in production** |
| **HMSP** | 264 | 100 | 2  (1st shift:0830hrs -1730hrs)  (2nd shift: 1700hrs -0200hrs) |
| **GHQ** | 60 | 66 | NA |
| **HLAM** | 308 | 382 | 2  (1st shift 0830hrs – 0830hrs)  (2nd shift: 0830hrs – 0830hrs) |
| **HMRC** | 60 | 40 | NA |
| **GDC** | 10 | 29 | NA |