| **Summary of Management**  **for Monitoring and Measurement Equipment** | | | | | | |
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| **Representative Product (Class)** | | HOYA iSert 151 (Class 4) | | | | |
| **Subject of Inspection** | **Item of Inspection** | **Name of Equipment** | **Control Number of Equipment** | **Period of Calibration** | **Recent Date of Calibration** | **Previous Date of Calibration** |
| Production-Material | Temperature | Water Bath no.1 | 05-800001-05 | 1 year | 03/13/2023 | 04/07/2020  04/05/2021  03/18/2022 |
| Production-Material | Temperature | Water Bath no.2 | 05-800002-05 | 1 year | 11/26/2021  (Transferred to HSOT Oct2022) | 12/17/2018  12/16/2019  12/07/2020 |
| Production-Material | Temperature | Water Bath no.3 | 05-800003-06 | 1 year | 9/21/2020  (Transferred to HSOP Nov2020) | 10/3/2018  9/26/2019 |
| Production-Material | Temperature & Pressure | Medium Capacity Evaporator no.1 | 05-800030-05 | 1 year | 1/3/2020  (Transferred to HLAM Dec2020) | 1/12/2018  1/7/2019 |
| Production-Material | Temperature | Air Oven no.1 | 05-800035-05 | 1 year | 7/14/2020  (Transferred to HSOT Nov2020) | 7/24/2018  7/22/2019 |
| Production-Material | Temperature | Air Oven no.2 | 05-800036-05 | 1 year | 11/23/2022 | 12/20/2020  11/30/2021  11/23/2022 |
| Production-Material | Temperature | Drying Oven no.1 | 05-800027-05 | 1 year | 12/27/2022 | 01/08/2020  01/05/2021  12/30/2021 |
| Production-Material | Temperature | Drying Oven no.2 | 05-800051-05 | 1 year | 01/03/2023 | 01/14/2020  01/12/2021  01/05/2022 |
| Production-Material | Temperature | Drying Oven no.3 | 05-800209-17 | 1 year | 12/26/2019  (Transferred to HSOT Dec2020) | 01/10/2018  01/03/2019 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.1 | 05-800080-06 | 1 year | 8/4/2020  (Transferred to HSOT Nov2020) | 08/16/2018  08/06/2019 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.2 | 05-800081-05 | 1 year | 08/23/2022  (Transferred to HSOT Oct2022) | 09/21/2018  09/18/2019  09/14/2020  09/06/2021 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.3 | 05-800082-05 | 1 year | 06/28/2022 | 08/04/2020  07/05/2021 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.4 | 05-800083-05 | 1 year | 06/28/2022 | 08/27/2020  07/05/2021 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.5 | 05-800084-06 | 1 year | 1/21/2020  (Transferred to HSOT Nov2020) | 09/17/2018  03/25/2019 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.6 | 05-800085-05 | 1 year | 08/02/2022 | 09/07/2020  08/10/2021 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.7 | 05-800086-05 | 1 year | 08/23/2022 | 01/22/2020  01/19/2021  09/06/2021 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.8 | 05-800087-05 | 1 year | 08/02/2022 | 09/07/2020  08/10/2021 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.9 | 05-800090-05 | 1 year | 8/4/2020  (Transferred to HSOT on Nov20) | 08/16/2018  08/06/2019 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.10 | \*105-800091-05 | 1 year | 08/03/2022  (Transferred to HSOT Oct2022) | 08/27/2020  10/28/2020  (HSVP-20036-VSR-00)  08/11/2021 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.11 | 05-800092-05 | 1 year | 06/29/2022 | 09/14/2020  07/06/2021 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.12 | 05-800093-06 | 1 year | 08/24/2022 | 04/16/2020  04/12/2021  09/07/2021 |
| Production-Material | Temperature/Pressure | Medium Capacity Evaporator no.2 | 05-800105-07 | 1 year | 12/29/2022 | 01/03/2020  12/31/2020  12/31/2021 |
| Production-Material | Temperature/Pressure/Recorder | Rotavapor Distillation Unit | 05-800151-12 | 1 year | 09/27/2022 | 10/08/2020  10/04/2021 |
| Production-Material | Weight | Precision Balance No.1 | 05-800175-15 | Half yearly | 12/15/2022 | 01/23/2020  07/20/2020  01/13/2021  07/07/2021  01/05/2022  06/21/2022 |
| Production-Material | Weight | Semi-Microbalance No.2 | 05-800211-17 | Half yearly | 12/15/2022 | 01/23/2020  07/20/2020  01/13/2021  07/07/2021  01/05/2022  06/21/2022 |
| Production-Material | Weight | Semi-Microbalance No.3 | 05-800212-17 | Half yearly | 12/15/2022 | 06/22/2020  12/14/2020  07/07/2021  01/05/2022  06/21/2022 |
| Production-Material | Weight | Precision Balance No.2 | 05-800213-17 | Half yearly | 11/29/2022 | 06/22/2020  12/14/2020  06/09/2021  12/06/2021  06/01/2022 |
| Production-Material | Weight | Big Size Balance No.2 | 05-800224-19 | Half yearly | 10/31/2022 | 6/12/2020  12/01/2020  05/25/2021  11/09/2021  05/06/2022 |
| PDIOL-Lens Production | Timer | Polishing Machine M1 | 02-900045-04 | 1 year | 12/31/2020 | 01/11/2018  01/07/2019  01/05/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M2 | 02-900046-04 | 1 year | 12/31/2020 | 01/11/2018  01/07/2019  01/05/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M3 | 02-900047-04 | 1 year | 12/31/2020 | 01/15/2018  01/09/2019  01/05/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M4 | 02-900048-04 | 1 year | 12/31/2020 | 01/10/2018  01/07/2019  01/05/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M5 | 02-900049-04 | 1 year | 01/06/2021 | 01/17/2018  01/09/2019  01/07/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M6 | 02-900050-04 | 1 year | 01/06/2021 | 01/18/2018  01/15/2019  01/14/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M7 | 02-900051-04 | 1 year | 01/05/2021 | 01/11/2018  01/08/2019  01/07/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M8 | 02-900052-04 | 1 year | 01/05/2021 | 01/11/2018  01/08/2019  01/07/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M9 | 02-900065-05 | 1 year | 01/03/2021 | 01/10/2018  01/08/2019  01/07/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M10 | 02-900066-05 | 1 year | 01/03/2021 | 01/10/2018  01/08/2019  01/06/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M11 | \*202-900067-05 | 1 year | 1/6/2020  (Inactive) | 01/15/2018  01/09/2019 |
| PDIOL-Lens Production | Timer | Polishing Machine M12 | \*202-900068-05 | 1 year | 1/6/2020  (Inactive) | 01/15/2018  0/09/2019 |
| PDIOL-Lens Production | Timer | Polishing Machine M27 | 02-900126-06 | 1 year | 01/06/2021 | 01/15/2018  01/09/2019  01/08/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M28 | 02-900127-06 | 1 year | 01/06/2021 | 01/18/2018  01/11/2019  01/08/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M23 | 02-900130-06 | 1 year | 01/12/2021 | 01/18/2018  01/17/2019  01/14/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M24 | 02-900131-06 | 1 year | 01/12/2021 | 01/18/2018  01/15/2019  01/14/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M29 | 02-900225-08 | 1 year | 12/27/2020 | 01/06/2018  01/04/2019  01/03/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M30 | 02-900226-08 | 1 year | 12/27/2020 | 01/06/2018  01/04/2019  01/03/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M31 | \*202-900227-08 | 1 year | 1/3/2020  (Inactive) | 01/06/2018  01/04/2019 |
| PDIOL-Lens Production | Timer | Polishing Machine M32 | \*202-900228-08 | 1 year | 1/3/2020  (Inactive) | 01/06/2018  01/04/2019 |
| PDIOL-Lens Production | Timer | Polishing Machine M33 | 02-900229-08 | 1 year | 12/29/2020 | 01/06/2018  01/04/2019  01/03/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M34 | 02-900230-08 | 1 year | 12/29/2020 | 01/06/2018  01/04/2019  01/03/2020 |
| PDIOL-Lens Production | Timer | Polishing Machine M35 | \*202-900231-08 | 1 year | 1/3/2020  (Inactive) | 01/06/2018  01/04/2019 |
| PDIOL-Lens Production | Timer | Polishing Machine M36 | \*202-900232-08 | 1 year | 1/3/2020  (Inactive) | 01/06/2018  01/04/2019 |
| Sterilization process | Temperature, Pressure  Humidity, Timer of Sterilization Chart Speed | EOG Sterilization Unit #1 | 03-900001-04 | 1 year | 09/22/2022 | 10/07/2020  10/06/2021 |
| Sterilization process | Temperature, Pressure  Humidity, Timer of Sterilization Chart Speed | EOG Sterilization Unit #2 | 03-900009-06 | 1 year | 10/19/2022 | 10/21/2020  10/19/2021 |
| Sterilization process | Temperature, Pressure  Humidity, Timer of Sterilization Chart Speed | EOG Sterilization Unit #3 | \*303-900019-15 | 1 year | 10/12/2021  (Inactive) | 10/22/2018  10/21/2019  10/14/2020 |
| Aeration process | Temperature & Air Exhaust Rate | Aerator Unit #1 | 03-900011-04 | 1 year | 03/23/2023 | 05/15/2020  05/03/2021  03/29/2022 |
| Aeration process | Temperature & Air Exhaust Rate | Aerator Unit #3 | 03-900013-07 | 1 year | 03/03/2023 | 04/02/2020  03/21/2021  03/02/2022 |
| Aeration process | Temperature & Air Exhaust Rate | Aerator Unit #4 | \*303-900017-12 | 1 year | 02/20/2022  (Inactive) | 03/14/2020  03/12/2021 |
| Sterilization Process | Temperature | Incubator | 03-900028-04 | 1 year | 08/18/2022 | 08/30/2021 |
| Quality Lab process | Incoming Inspection | HPLC system (High Performance Liquid Chromatograph) | 01-800013-05 | 1 year | 06/30/2022 | 07/17/2020  07/09/2021 |
| Quality Lab process | Incoming Inspection | FTIR (Fourier Transform Infrared Spectroscopy) | 01-800014-05 | 1 year | 01/03/2023 | 01/16/2020  01/15/2021  01/10/2022 |
| Quality Lab process | Incoming Inspection | Gas Chromatograph | 01-800012-05 | 1 year | 04/14/2022 | 04/17/2020  04/16/2021 |
| Quality Lab process | Incoming Inspection & In-Process Inspection | UV spectrometer | 01-800011-05 | 1 year | 04/26/2022 | 05/11/2020  05/05/2021 |
| Quality Lab process | In-Process Inspection | Auto Durometer | 01-800018-05 | 1 year | 07/28/2022 | 08/19/2020  08/17/2021 |
| Quality Lab process | Environmental test | Incubator | 01-900005-04 | 1 year | 03/14/2023 | 03/31/2020  03/23/2021  03/17/2022 |
| Quality Lab process | Environmental test | Incubator | 01-900006-04 | 1 year | 03/14/2023 | 03/31/2020  03/23/2021  03/17/2022 |
| Quality Lab process | Environmental test | Incubator | \*401-900007-04 | 1 year | 08/10/2021  (Transferred to Sterilization Aug2021) | 03/31/2020  03/23/2021 |
| Quality Lab process | Product release test | Incubator | \*501-900257-09 | 1 year | 08/10/2021  (Decommissioned on 18 Aug 2021) | 03/31/2020  03/24/2021 |
| Quality Lab process | Product release test | Incubator | \*501-900022-04 | 1 year | 03/17/2022  (Decommissioned on 20 Jun 2022 | 03/31/2020  03/24/2021 |
| Quality Lab process | Product release test | Gas Chromatograph | \*601-900026-04 | 1 year | 01/10/2023 | 01/08/2020  01/06/2021  01/11/2022 |
| Quality Lab process | Environmental test | Particle Counter | \*701-900027-04 | 1 year | 05/19/2020  (Decommissioned on 28 May 2021) |  |
| Quality Lab process | Environmental test | Particle Counter | \*808-900015-16 | 1 year | 03/02/2023 | 02/28/2020  03/09/2021  03/10/2022 |
| Quality Lab process | Environmental test | Particle Counter | 06-900113-15 | 1 year | 07/29/2022 | 07/24/2020  07/19/2021 |
| Quality Lab process | Environmental test | Air Tester | 08-900046-18 | 1 year | 07/27/2022 | 08/04/2020  08/02/2021 |
| Quality Lab process | Environmental test | Air Tester | 08-900047-18 | 1 year | 10/26/2022 | 11/24/2020  11/16/2021 |
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Remark:

* \*105-800091-05 – Recalibration on 10/28/2020 due to recorder replacement. Refer to Validation Document (HSVP-20036) for the qualification details.
* \*2 Polishing Machine M11, M12, M31, M32, M35 & M36 have been inactive upon reaching their calibration due dates.
* The rest of the Polishing machine have been inactive upon reaching their calibration due dates since PDIOL and Final Inspection sections have ceased according to email announcement made by Management on 22 July 2021
* \*303-900019-15 and 03-900017-12: Equipment have been inactive upon reaching their calibration due dates.
* Sterilization and Packing production were ceased on 17 January 2023 according to official email announcement.
* \*401-900007-04 - Incubator for Environmental Monitoring 01-900007-04 was transferred to Sterilization team on 18 Aug 2021 for SCBI test project (ID No. under Sterilization team is 03-900028-04).

Last calibration of incubator 01-900007-04 was on 10 Aug 2021.

* \*501-900257-09 and 01-900022-04 Incubators for BI test were decommissioned on 18 Aug 2021 and 20 Jun 2022 respectively following from the implementation of SCBI test on 15 Nov 2021.

Note: SCBI test replaced BI test.

Last calibration of Incubator 01-900257-09 was on 10 Aug 2021.

Last calibration of Incubator 01-900022-04 was on 17 Mar 2022.

* \*6Calibration of Gas Chromatograph 01-900026-04 in year 2022 was delayed due to delayed arrival of standards / parts. Nevertheless, the delay was pre-informed and sign of “Equipment cannot be used” was tagged to the equipment.
* \*7Particle Counter 01-900027-04 was decommissioned on 28 May 2021 due to equipment beyond repair as found out when it was sent out for calibration on 12 May 2021. The faulty part was the calibration alarm (hardware) and no replacement part was available as Particle Counter model was already discontinued in year 2018. Airborne Particulate test reports for cleanrooms were traced back and it was confirmed that 01-900027-04 had not been used since year 2019 and its last valid calibration was done on 19 May 2020.
* \*8Though calibration of Particle Counter 08-900015-16 in year 2021 was carried out on 9 Mar 2021, equipment was sent out for calibration on 26 Feb 2021. Similarly for calibration in year 2022, equipment was sent out for calibration on 4 Mar 2022.

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| **HOYA Medical Singapore Pte. Ltd** | |
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| **Senior Quality Manager:**  Angie LAI | **Quality Representative :**  Siva Kumar PONNUSAMY |
| **Signed Date :** | **Signed Date :** |