| **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**  **(Month/Day/Year)** | **Previous Date of Calibration**  **(Month/Day/Year)** |
| 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 HLAM Oct2022) | 12/17/2018  12/16/2019  12/07/2020 |
| Production-Material | Temperature | Water Bath no.3 | 05-800003-06 | 1 year | 09/21/2020  (Transferred to HLAM Nov2020) | 10/03/2018  09/26/2019 |
| Production-Material | Temperature & Pressure | Medium Capacity Evaporator no.1 | 05-800030-05 | 1 year | 01/03/2020  (Transferred to HLAM Dec2020) | 01/12/2018  01/07/2019 |
| Production-Material | Temperature | Air Oven no.1 | 05-800035-05 | 1 year | 07/14/2020  (Transferred to HLAM Nov2020) | 07/24/2018  07/22/2019 |
| 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 HLAM Dec2020) | 01/10/2018  01/03/2019 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.1 | 05-800080-06 | 1 year | 08/04/2020  (Transferred to HLAM 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 HLAM 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 | 01/21/2020  (Transferred to HLAM 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 | 08/04/2020  (Transferred to HLAM on Nov20) | 08/16/2018  08/06/2019 |
| Production-Material | Temperature/Pressure/Recorder | Pressurized Oven no.10 | 05-800091-05 | 1 year | 08/03/2022  (Transferred to HLAM Oct2022) | 08/27/2020  **\*1**10/28/2020  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 | **\*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  **\*3**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 | 06/12/2020  12/01/2020  05/25/2021  11/09/2021  05/06/2022 |
| 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 | 04/05/2023 | 04/17/2020  04/16/2021  04/14/2022 |
| Quality Lab process | Incoming Inspection & In-Process Inspection | UV spectrometer | 01-800011-05 | 1 year | 04/19/2023 | 05/11/2020  05/05/2021  04/26/2022 |
| 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  (03-900028-04) | 1 year | 08/28/2022  (Transferred to Sterilization 18 Aug 2021) | 03/31/2020  03/23/2021  08/10/2021  08/30/2021 |
| 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 May2021) | Refer under Remark in detail |
| Quality Lab process | Environmental test | Particle Counter | 08-900015-16 | 1 year | 03/02/2023 | 02/28/2020  \*803/09/2021  \*803/10/2022 |
| Quality Lab process | Environmental test | Particle Counter | 06-900113-15 | 1 year | \*907/29/2022 | 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 |

Remark:

\*1) 05-800091-05 – Recorder was not used from 28 Aug 2020 to 27 Oct 2020 due to Printing Pen Mechanism of recorder was faulty.

Re-calibration was conducted on 28 Oct 2020 due to recorder replacement.

\*2) 05-800211-17- equipment was found faulty on 02 Feb 2023 and decommissioned on 11 April 2023.

\*3) 05-800212-17 – Equipment was not used from 09 June 2021 to 06 July 2021 due to faulty. Re-calibration was conducted

on 07July 2021.

\*4) 01-900007-04 – Last calibration under Quality Lab process was on 10 Aug 2021. Subsequently, Equipment was transferred to Sterilization team on 18 Aug 2021 for SCBI test project (ID No. under Sterilization team is 03-900028-04).

\*5) 01-900257-09 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.

\*6) 01-900026-04 -Calibration was delayed until 10 Jan 2022 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.

\*7) 01-900027-04 -Equipment 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.

\*8) 08-900015-16 - Equipment was sent out for calibration on 26 Feb 2021but calibration was carried out on 09 Mar 2021 at vendor site. Similarly, equipment was sent out for calibration on 04 Mar 2022, but calibration was carried out 10 Mar 2022 at vendor site.

\*9) 06-900113-15 -Equipment was belonged to Manufacturing Engineering team. Initial plan was not renewed for the calibration due to no longer perform airborne particulate count for the projects. Subsequently, re-calibration was performed on 29 July 2022 when QL team require to use the equipment for the routine particle count monitoring.

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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 :** |