AO NAME

AO HEAD OFFICE ADDRESS

Attn: AO REPRESENTATIVE’S NAME

AO REPRESENTATIVE’S TITLE

**RE: Authorization to perform audits under the Medical Device Single Audit Program (MDSAP)**

Dear Mr./Ms. AO REPRESENTATIVE’S NAME

Considering:

1. The Statement of Cooperation between the Australian Therapeutic Goods Administration (TGA), the Brazilian Health Surveillance Agency (ANVISA), the Canadian Health Products and Food Branch (Health Canada), and the United States Food and Drug Administration (FDA) regarding cooperation in the Medical Device Single Audit Program (MDSAP), signed in Manaus, Brazil on November 27th, 2012;
2. The MDSAP Functional Statement (Document #: MDSAP P0001) among FDA, TGA, ANVISA, Health-Canada, and Japan’s Ministry of Health, Labour and Welfare and the Japanese Pharmaceuticals and Medical Devices Agency (MHLW/PMDA);
3. The application file received on DATE;
4. The assessments of the compliance of AO NAME to the requirements set in the IMDRF MDSAP WG documents N3[[1]](#footnote-1) and N4[[2]](#footnote-2), performed between DATE and DATE, at your head office and at your critical locations in XXX and XXX;
5. The recommendation from the assessment team leaders; and,
6. The review of the assessment file by the Assessment Program Manager.

TGA, ANVISA, Health Canada, MHLW/PMDA and the FDA grant AO NAME with the authorization to perform Medical Device Single Audit Program audits.

As part of the initial assessment program, MDSAP assessors must witness the first three MDSAP audits performed by AO NAME.

This authorization, granted by the signatories of the Statement of Cooperation and the MDSAP Functional Statement on START DATE, takes effect the same day.

This authorization is conditional upon continued compliance with MDSAP requirements, and the additional conditions documented in the Schedule 1 (if any) and is valid FOR 2 YEARS.

Signature-\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CHAIRPERSON NAME:

Chair of the Regulatory Authority Council

Date:

Assessment Program Manager: APM NAME & TITLE

Postal Address: APM Address

Tel.: APM Phone #

Email.: APM Email address

**Schedule 1: Conditions**

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| --- | --- |
| **Condition** | **Due date to present the fulfilment of the requirements identified in the condition** |
| 1. | YYYY-MM-DD |
| 2. | YYYY-MM-DD |
| 3. | YYYY-MM-DD |
| 4. | YYYY-MM-DD |

1. IMDRF MDSAP WG N3 - Requirements for Medical Device Auditing Organizations for Regulatory Authority

   Recognition [↑](#footnote-ref-1)
2. IMDRF MDSAP WG N4 - Competence and Training Requirements for Auditing Organizations [↑](#footnote-ref-2)