MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DEKRA Certification B.V.
Meander 1051
6825 MJ Arnhem
Netherlands

Attn: Brent Anderson
Sr. Project Manager

RE: Recognition as Auditing Organization under the Medical Device Single Audit Program (MDSAP)

Ref: 2018-02-07-DEKR-REC

Dear Mr. Anderson,

Considering:

1. The Statement of Cooperation among the United States Food and Drug Administration (US FDA), the Australian Therapeutic Goods Administration (TGA), the Brazilian Health Surveillance Agency (ANVISA), and the Canadian Health Products and Food Branch (Health-Canada) 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. 002) among US 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 assessments of the compliance of DEKRA Certification B.V. to the requirements set in the IMDRF MDSAP WG documents N3[1] and N4[2], performed between 2015-12-11 and 2017-09-15, as listed in schedule 1;

4. The recommendation from the assessment team leaders; and

5. The review of the assessment file by the Technical Review and Recommendation Committee and the endorsement of their decision by the MDSAP Regulatory Authority Council.

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[1] IMDRF MDSAP WG N3 - Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition

[2] IMDRF MDSAP WG N4 - Competence and Training Requirements for Auditing Organizations

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TGA, ANVISA, Health-Canada, MHLW/PMDA and the US FDA, as listed on the Schedule 2, decided to recognize DEKRA Certification B.V. as an auditing organization under the MDSAP.

This decision by the signatories of the Statement of Cooperation and the MDSAP Functional Statement, on 2018-02-07, takes effect the same day.

The recognition is conditional upon continued compliance with MDSAP requirements, and the additional conditions documented in the Schedule 3 (if any), and is valid for a period of four (4) years starting on the date of decision and expiring on 2022-02-06.

Note that the effectiveness of corrections and corrective actions for the following nonconformities will be reviewed during the next surveillance assessment or witnessed audit:
- 2016-07-29-ANC-DEKR-01 (CL1)
- 2016-07-29-ANC-DEKR-04 (CL1)
- 2016-07-29-ANC-DEKR-02 (CL1)
- 2016-07-29-ANC-DEKR-03 (CL1)
- 2017-07-14-ANC-DEKR-01 (WA2)

Maria Angela da Paz

Assinado de forma digital por Maria Angela da Paz
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Dados: 2018 02 16 09 05 11 -02'00'

Maria Angela da Paz:
Chair of the Regulatory Authority Council
Date: 2018-02-07

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Schedule 1: List of assessment activities supporting the recognition decision

Assessment Report	Assessment Starting Date	Assessment Ending Date	Assessment Activity Type	Visited Location
2016-02-12-ASR-DEKR.001	2015-12-11	2016-01-12	Aplpication Review	NA
2016-02-12-ASR-DEKR.001	2016-02-15	2016-04-07	Stage 1 Assessment	NA
2016-04-07-ASR-DEKR.001	2016-04-04	2016-04-07	Stage 2 Assessment	Head Office
2016-07-27-ASR-DEKR.001	2016-08-27	2016-08-29	Assessment of Critical Location	120 Welsh Road, Suite 210 North Wales, PA 19454 - USA (assessed remotely)
2016-08-02-ASR-DEKR.001	2016-08-02	2016-08-04	Assessment of Critical Location	1850 Gateway Blvd Suite Concord, CA 94520 - USA
2017-02-06-WIT-DEKR-078351396.001	2016-02-06	2017-03-27	Witnessed Audit 1	NA*
2017-05-23-WIT-DEKR - 030200852.001	2017-05-23	2017-07-14	Witnessed Audit 2	NA*
2017-07-31-WIT-DEKR-936754092.002	2017-07-31	2017-09-15	Witnessed Audit 3	NA*

* Witnessed audits take place at a medical device manufacturer, not part of the auditing organization

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Schedule 2: Contact information at the recognizing regulatory authorities, by country

Country	Contact Information at the Recognizing Regulatory Authority	
Australia	Australian Government Department of Health Therapeutic Goods Administration (TGA) Office of Manufacturing Quality PO Box 100 Woden ACT 2606 Australia	
Brazil	ANVISA – Brazilian Health Regulatory Agency Setor de Indústria e Abastecimento (SIA) Trecho 5, Área Especial 57 / Lote 200 Brasília (DF) CEP 71205-050 Brazil	
Canada	Health Canada Therapeutic Products Directorate Health Products and Food Branch Medical Device Bureau Address Locator: 3106B Ottawa, Ontario K1A 0K9 Canada	
Japan	Japan's Ministry of Health, Labour and Welfare Ministry of Health, Labour and Welfare Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau 1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo 1008616 Japan	Pharmaceuticals and Medical Devices Agency Office of Manufacturing/Quality and Compliance- Division of Registered Certification Body Assessment Shin-kasumigaseki Bldg. 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
United states of America	Food and Drug Administration (FDA) Center of Device and Radiological Health Office of Compliance / Division of International Compliance Operations / Medical Device Single Audit Program 10903 New Hampshire Avenue Silver Spring, MD 20993 USA	

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Schedule 3: Conditions

Nil