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

Attn: Adriano Mulloni

RE: Re-recognition as Auditing Organization under the Medical Device Single Audit Program (MDSAP)

Dear Mr. Mulloni,

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) 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 DEKR to the requirements set in the IMDRF MDSAP WG documents N3[1] and N4[2], performed between 2018-04-11 and 2021-09-10, 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.

[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

TGA, ANVISA, Health-Canada, MHLW/PMDA and the US FDA, as listed on the Schedule 2, decided to re-recognize the National Standards Authority of Ireland as an auditing organization under the MDSAP.

This decision by the signatories of the Statement of Cooperation and the MDSAP Functional Statement, on 2022-02-07, takes effect the same day.

The recognition is conditional upon continued compliance with MDSAP requirements and is valid for a period of four (4) years starting on the date of decision and expiring on 2026-02-06.

-Signature- Kenichi Ishibashi

CHAIRPERSON NAME: Kenichi Ishibashi
Chair of the Regulatory Authority Council
Date: 2023-07-21

Assessment Program Manager: Marc-Henri Winter
Program analyst, Regulatory Inspections and Audits Team
Division of Regulatory Programs 2, Office of RegulatoryPrograms
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration

Tel.: +1 (301) 796-6097
Email.: Marc-Henri.Winter@fda.hhs.gov

Schedule 1: List of assessment activities supporting the recognition decision

Assessment Report	Assessment Starting Date	Assessment Ending Date	Assessment Activity Type	Visited Location
2018-04-11-ASR-DEKR-001	2018-04-11	2018-04-13	Surveillance Assessment	Arnhem, the Netherlands
2019-04-15-ASR-DEKR.001	2019-04-15	2019-04-17	Surveillance Assessment	Arnhem, the Netherlands
2020-08-18-ASR-DEKR-001	2020-08-18	2020-08-21	Surveillance Assessment	Arnhem, the Netherlands
2021-09-07-ASR-DEKR.001	2021-09-07	2021-09-10	Re-recognitioin Assessment	Arnhem, the Netherlands
2018-09-25-WIT-DEKR-120981337.001	2018-09-25	2018-09-28	Witnessed Audit	NA*
2019-06-24-WIT-DEKR-482491177.001	2019-06-24	2019-09-26	Witnessed Audit	NA*
2020-05-12-WAR-DEKR-FertiPro	2020-05-13	2020-05-15	Witnessed Audit	NA*

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

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	Medical Devices Directorate 5th floor – Holland Cross, Tower A 11 Holland Avenue Address Locator: 3002A 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 Standards and Compliance for Medical Devices- 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