DQS Medizinprodukte GmbH
August-Schanz-Str. 21
Frankfurt am Main
D-60433
Germany

Attn: Maxim Shkolnikov
Program Manager MDSAP

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

Dear Mr. Shkolnikov

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 P0001.002) 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 2015-11-10;

4. The assessments of the compliance of DQS Medizinprodukte to the requirements set in the IMDRF MDSAP WG documents N3[1] and N4[2], at your head office;

5. The original authorization granted during the MDSAP Pilot on 2016-12-08.

6. The recommendation from the assessment team leaders; and,

[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

7. The review of the assessment file by the Assessment Program Manager.

TGA, ANVISA, Health Canada, MHLW/PMDA and the FDA grant DQS Medizinprodukte with an extension of the authorization to perform Medical Device Single Audit Program audits.

During this extension, MDSAP assessors must witness three MDSAP audit conducted by DQS Medizinprodukte. After the recognition criteria has been met, a review by the Technical Review and Recognition Committee will determine the status of recognition under MDSAP.

This authorization, granted by the signatories of the Statement of Cooperation and the MDSAP Functional Statement on 2017-01-01, takes effect the same day.

This authorization is conditional upon continued compliance with MDSAP requirements and is valid until 2018-12-31.

FABIO PEREIRA QUINTINO

Assinado de forma digital por FABIO PEREIRA QUINTINO
DN: cn=FABIO PEREIRA QUINTINO, c=BR, o=ICP-Brasil, ou=Pessoa Fisica A3, ARSERPRO, Autoridade Certificadora SERPROACF
Dados: 2017.03.31 10:41:27 -03'00'

Fábio Pereira Quintino:
Chair of the Regulatory Authority Council
Date: 2017-03-30

This letter corrects an inaccuracy on the original letter issued on 2017-01-02

Assessment Program Manager: Marc-Henri Winter, Staff Fellow
Postal Address: 10903 New Hampshire Avenue, Building 66, Room 3615, Silver Spring, MD 20993
Tel.: 301-796-6097
Email: marc-henri.winter@fda.hhs.gov