



SGS North America Inc.
620 Old Peachtree Road
SUITE 100
Suwanee, Georgia 30024
United States

Applicant Declaration

Applicant Legal Business Name	Fresenius Medical Care AG		
Address	Hafenstr. 9, 97424 Schweinfurt, Germany		
FRN	0035959857		
Grantee Code	2BK5J	FCC ID:	2BK5J-DGF109FME
Authorized Contact Name	Alexander Schreiber		
Contact Phone	+49 (9721) 678-67806	Contact Email	alexander.schreiber@freseniusmedicalcare.com

I, the undersigned, certify that I am an authorized signatory for the Applicant and therefore declare;

- a) in accordance with 47CFR2.911(d), all of the statements herein and the exhibits attached hereto are true and correct to the best of my knowledge and belief.
- b) in accepting a Grant of Equipment Authorization issued by a TCB, under the authority of the FCC, as a result of the representations made in this application, the Applicant is responsible for:
 - (1) labeling the equipment with the exact FCC ID as specified in this application,
 - (2) compliance statement labeling pursuant to the applicable rules,
 - (3) compliance of the equipment with the applicable technical rules,
- c) if the Applicant is not the actual manufacturer of the equipment, appropriate arrangements have been made with the manufacturer to ensure that production units of this equipment will continue to comply with the FCC's technical requirements.
- d) in accordance with 47 CFR 2.909 and KDB394321, the Applicant has read, understood and agrees to accept that they are the responsible party and agree to abide by their responsibilities as specified under 47 CFR 2.909 and KDB394321.
- e) in accordance with ISO 17065, FCC KDB641163, FCC KDB610077, KDB394321 and RSP-100, the Applicant has read, understood, accepts and agrees to abide by the post market surveillance requirements.
 - (1) the Applicant understands, accepts and agrees that a sample may be requested for surveillance testing.
 - (2) the Applicant **shall** make provisions to always have a production sample available upon request by SGS, FCC and/or ISED.
 - (3) the Applicant **shall**, upon request by SGS, at the Applicant's expense, provide a production sample of the requested product to SGS, FCC and/or ISED as instructed. The sample shall include all support devices, cables, software, accessories or other hardware or software required for evaluation, review, certification and audit surveillance of products certified by SGS.
- f) neither the Applicant nor any party to the application is subject to a denial of Federal benefits, that includes FCC benefits, pursuant to Section 5301 of the Anti-Drug Abuse Act of 1988, 21 U.S.C. §862 because of a conviction for possession or distribution of a controlled substance. See 47CFR 1.2002(b) for the definition of a "party" for these purposes.
- g) the Applicant has read, understood, accepts and agrees to abide by the SGS North America, Inc. terms and conditions as specified in the TCB Application Form 731 (QSF27-14-01).

Link to CFRs: <https://www.fcc.gov/wireless/bureau-divisions/technologies-systems-and-innovation-division/rules-regulations-title-47>

Link to KDBs: <https://apps.fcc.gov/oetcf/kdb/index.cfm>

Link to RSP-100: <https://www.ic.gc.ca/eic/site/smt-gst.nsf/eng/sf01130.html>

Link to the Covered List: [Covered List](#)

Attestation Statements Part 2.911(d)(5)(i)&(ii)

Statement for 47 CFR section 2.911(d)(5)(i)

[Fresenius Medical Care AG] ("the applicant") certifies that the equipment for which authorization is sought **is not** "covered" equipment prohibited from receiving an equipment authorization pursuant to section 2.903 of the FCC rules.

[Fresenius Medical Care AG] ("the applicant") certifies that the software to be loaded prior to marketing of the equipment for which authorization is sought does not include cybersecurity or anti-virus software produced or provided by Kaspersky Lab, Inc. or any of its successors and assignees, including equipment with integrated Kaspersky Lab, Inc. (or any of its successors and assignees) cybersecurity or anti-virus software pursuant to [DA-24-886](#) and KDB 986446 D01 Covered Equipment Guidance section B(2a).



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the device is not capable of storing or running software listed on the covered list and therefore is not inherently compliant.

Statement for 47 CFR section 2.911(d)(5)(ii)

[[Fresenius Medical Care AG](#)] (“the applicant”) certifies that, as of the date of the filing of the application, the applicant **is not** identified on the Covered List, established pursuant to §1.50002, as a specifically named entity or any of its subsidiaries or affiliates that producing “covered” equipment.

Applicant Signature:			Date: 按一下或點選以輸入日期。 2025/05/09
Print Name:	Alexander Schreiber		
Title:	Senior Manager Design Quality Assurance		

**NOTE: This declaration cannot be signed by an Agent, it shall be signed by an authorized person listed in the FCC database*