

117TH CONGRESS
2D SESSION

S. 4391

To establish rules for export certification of devices manufactured outside of the United States.

IN THE SENATE OF THE UNITED STATES

JUNE 14, 2022

Mr. CASSIDY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To establish rules for export certification of devices manufactured outside of the United States.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Correcting a Lack of
5 Efficient, Adequate, and Reasonable Documentation Act”
6 or the “CLEAR Documentation Act”.

7 **SEC. 2. CERTIFICATION OF IMPORTED DEVICES.**

8 Section 801(e)(4)(E) of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 384(e)(4)) is amended by strik-
10 ing clause (iii) and inserting the following:

1 “(F)(i) The Secretary shall issue a certification under
2 subparagraph (A) for a device manufactured by an estab-
3 lishment located outside of the United States that is reg-
4 istered under section 510(i), if the device—

5 “(I) is listed pursuant to section 510(j);

6 “(II) has been approved under section 515 or
7 cleared under section 510(k), or is not required to
8 submit a premarket report pursuant to subsection
9 (l) or (m) of section 510;

10 “(III) is imported or offered for import into the
11 United States; and

12 “(IV) otherwise meets the requirements of this
13 Act.

14 “(ii)(I) A certification for a device described in clause
15 (i)—

16 “(aa) shall be subject to the fee described in
17 subparagraph (B); and

18 “(bb) notwithstanding subparagraph (C), shall
19 address and include the same material information
20 as a Certificate to Foreign Government, and shall
21 have a document title that includes the words ‘Cer-
22 tificate to Foreign Government’.

1 “(iii) The requirements and procedures of subpara-
2 graph (E) shall apply to a denial of a certification under
3 this subparagraph.”.

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